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Flexible and semi-rigid endoscope processing in health care facilities

AAMI
Advancing Safety in Health Technology

Flexible and semi-rigid endoscope processing in health care facilities

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Abstract: Provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use.

Keywords: endoscope processing, endoscope storage, flexible endoscopes, semi-rigid endoscopes, high-level disinfection, sterilization, leak testing, endoscope inspection

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Contents

Page

Tables

Figures

Committee representation

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Foreword

This standard was developed by the AAMI Endoscope Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide guidelines for precleaning, transport, leak testing, cleaning, high-level disinfection, liquid chemical sterilization, packaging, sterilization, and storage of flexible and semi-rigid endoscopes. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these devices and accessories.

The first edition of this standard was published as an American National Standard in 2015. This edition technically revises and replaces the first edition.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

This standard should be considered flexible and dynamic. As technology advances and as new data are brought forward, the standard will be reviewed and, if necessary, revised.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care facilities* (ANSI/AAMI ST91:2021), but it does provide important information about the development and intended use of the document.

Introduction

Reusable flexible and semi-rigid endoscopes are used in various body cavities for diagnostic and therapeutic procedures. All endoscopy procedures pose risks to patients. The introduction of pathogens through use of contaminated endoscopes is an appreciable risk that can be mitigated. Pathogens can be introduced when there are breaches of host barriers, person-to-person transmission of pathogens (e.g., Escherichia coli), or transmission of environmental pathogens (e.g., Pseudomonas aeruginosa). Further consequences of inadequate device processing can include device damage and adverse reactions in patients.

Of greatest concern is the multiple and growing number of reports of multi-drug-resistant organism (MDRO) transmission resulting in patient infection (Galdys, 2019 [158]; Kumarage, 2019 [203]; Jørgensen, 2016 [192]) and in some cases high rates of mortality (FDA MDR 8379810, 2019 [322]; Humphries, 2017 [177]; Ross, 2015 [270]; FDA, 2015c [335]). These outbreaks have led to Food and Drug Administration (FDA) safety alerts (FDA, 2018a [332]; FDA, 2015a [333]; FDA, 2015b [334]; FDA, 2015c [335]), Centers for Disease Control and Prevention (CDC) statements (CDC/FDA, 2015 [110]; CDC, 2015 [111]; FDA/CDC, 2018 [341]), professional guidelines and position statements updates, and heightened awareness by the public. Additional outbreaks have been reported related not only to duodenoscopes (Rauwers, 2019 [262]; Bourigault, 2018 [96]; Potron, 2017 [257]; Epstein, 2014 [145]), but also to gastroscopes (Bajolet, 2013 [74]), ureteroscopes (Kumarage, 2019 [200]; Chang, 2013 [102]), cystoscopes (Sorbets, 2019 [296]; Ottawa Public Health, 2019 [250]; Jimeno, 2016 [184]; Wendelboe, 2008 [374]), colonoscopes (Reddick, 2017 [264]; Gonzalez-Candelas, 2017 [165]) and bronchoscopes (Galdys, 2019 [158]; Alipour, 2017 [64]; Jørgensen, 2016 [192]; Guy, 2014 [169]; Kovaleva, 2013 [202]). What is very concerning regarding outbreaks related to MDROs is that failures in the processing or the equipment could not always be identified. The facilities were following the guidelines and manufacturers' written instructions for use (IFU) (Galdys, 2019 [158]; Humphries, 2017 [177]).

Endoscopic transmission of infection

Although flexible endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine, as illustrated above, numerous healthcare-associated infections (HAIs) have been linked with the use of contaminated endoscopes. Prior to the multiple documented outbreaks in the last few years, the risk of endoscope-related patient infection was considered to be relatively rare. Now there are multiple published reports of endoscope processing lapses, including tens of thousands of patient exposures both in the United States and other countries (Dirlam-Langlay, 2013 [135]; Ottawa Public Health, 2019 [250]; Galdys, 2019 [158]; FDA MDR 8811666, 2019 [346]; Ross, 2014 [270]; Epstein, 2014 [145]; US Department of Veterans Affairs, 2009 [131]). In addition, there are other reports of potential patient exposures to contaminated endoscopes in the media and other public databases that have not been published in peer-reviewed literature (U.S. Senate Report, 2016 [364]; CMS, 2015a [120]; CMS, 2015b [121]).

Health care facilities and manufacturers are required to report to the FDA MAUDE (Manufacturer and User Facility Device Experience) database any information that reasonably suggests that a device (such as an endoscope, accessory, or automated endoscope reprocessor) has caused or contributed to a death, injury, or serious illness of a patient. The MAUDE database contains numerous references to infections suspected to have occurred after lapses in processing or as a result of ineffective processes (e.g., FDA MDR 8683917, 2019 [319]; FDA MDR 8524645, 2019 [321]; FDA MDR 8379810, 2019 [322]; FDA MDR 8242610, 2019 [323].

Multiple peer-reviewed publications in several countries, including the United States, have documented breaches in processing that have led to patient exposure to improperly processed flexible and semi-rigid endoscopes and have caused serious infections (Gonzalez-Candelas et al., 2010 [165]; Carbonne et al., 2010 [101]; Aumeran et al., 2010 [72]; Robertson, 2017 [268]; Reddick, 2017 [264]; Kumarage, 2019 [203]; FDA MDR 8379810, 2019 [322]; Kovaleva et al., 2013 [202]; Rubin et al., 2018 [271]).

In many reports of patients being exposed to contaminated endoscopes, the patients were not tested for all pathogenic organisms but only HIV or hepatitis B viruses, despite documented outbreaks of non-viral pathogens. Published reports support the conclusion that current risk estimates are outdated and inaccurate (Ofstead et al., 2013 [243]; Dirlam-Langlay et al., 2013 [135]). The true risk of patient infection related to flexible endoscopy procedures has recently been reported to be higher than previously believed (Wang, 2018 [371]). In addition, there are many reports of outbreaks related to contaminated endoscopes (Seoane-Vazquez, 2006 [289]; Kovaleva et al., 2013 [202];

Rubin et al., 2018 [271]; Galdys 2019 [158]; Kumarage, 2019 [203]; Sorbets, 2019 [296]). The FDA provided interim results from mandated post market surveillance studies on duodenoscope contamination. These results indicate that up to 5.4 % of duodenoscopes sampled after appropriate processing were contaminated with high-concern organisms (FDA, 2019a [325]; FDA, 2019b [326]; FDA, 2019c [327]; FDA, 2019d [336]). These results led the FDA to recommend adoption of new technologies and designs of duodenoscopes to address the problem.

Audits conducted of facilities that perform GI endoscopic procedures have found widespread lapses in infection prevention and control, including endoscope processing, and in some cases, endoscopes were not processed in accordance with guidelines (Dirlam-Langlay et al., 2013 [135]; The Joint Commission, 2017 [186]; Armellino, 2018 [70]; Ofstead, 2018(a) [237]; Ofstead, 2018(b) [242]; Ofstead, 2017 [238]).

A 2013 northeastern Illinois infectious outbreak of New Delhi metallo-β-lactamase (NDM) producing Carbapenem-resistant Enterobacteriaceae (CRE) was linked with contaminated endoscopes used to perform endoscopic retrograde cholangiopancreatography (ERCP). A total of 39 patients were identified as infected (Epstein et al, 2014 [145]). Further outbreaks were similarly linked to duodenoscopes in Boston (Shenoy et al., 2019 [291]), Pittsburgh (McCool et al., 2012 [209]), Seattle (Wendorf et al., 2015 [375]), and Los Angeles (Rubin and Murthy, 2016 [273]; Smith et al., 2015 [294]; Humphries, 2017 [177]) known through media and FDA reporting.

Effects of endoscopy-related infection outbreaks and other adverse events can include the following:

- Spread of microorganisms from patient to patient by contaminated or improperly processed flexible and semi-rigid endoscopes or by malfunctioning equipment or between patients and endoscopy personnel (exogenous infections).
- Spread of microorganisms during an endoscopy procedure from the GI tract through the bloodstream to susceptible organs or spread of microorganisms to adjacent tissues that are breached as a result of the endoscopic procedure.
- Patient or healthcare worker injury related to chemical residue remaining on devices after the procedure or processing.
- Patient injury or delay in treatment related to damaged devices that are difficult to use because of mishandling or inadequate processing.

Mitigating these risks begins with the correct handling procedures in preparation for processing, including precleaning steps at the point of use (e.g., bedside procedures), disassembly of parts, and safe transport.

Cleaning according to the specific manufacturer's written IFU is required to remove clinical soil and other materials prior to the antimicrobial processes of high-level disinfection or sterilization. Growth of gram-negative bacteria and other potential pathogens can be prevented by complete drying after high-level disinfection (Alfa, 1991 [53]; Ofstead et al., 2018 [242]; Perumpail, 2019 [254]).

Cleaning is a multi-step process and is critical not only to ensure that subsequent processing steps can be effective but also to remove materials that can lead to adverse patient reactions. Cleaning, which reduces clinical soil, is then followed by disinfection or sterilization to inactivate microbial contaminants. Critical devices are devices that are introduced directly into the bloodstream, or which contact a normally sterile tissue or body space during use and for which sterilization is required. Semi-critical devices come in contact with mucous membranes or non-intact skin. These items should be thoroughly cleaned and then sterilized. If sterilization is not possible, high-level disinfection is the minimum advised processing method (FDA, 2015 [334]). Historically, because of cost and logistic needs, the standard of care for gastroenterology and other endoscopes used in procedures performed outside of operating rooms has been high-level disinfection (SGNA, 2018 [297]; ASGE, 2017 [28]). It is advised that flexible and semi-rigid endoscopes to be used in semi-critical applications be sterilized prior to use (Spaulding, 1972 [301]; FDA, 2015 [334]; AORN, 2018 [367]).

Evidence to support sterilizing all flexible endoscopes (semi-critical and critical) includes:

a) high microbial load after patient procedure (Alfa, 2014 [56]; Ofstead, 2015 [235]; Fushimi, 2013 [157]);

b) complex design of flexible endoscopes;

c) risk for biofilm formation (Alfa, 2017 [51], [62]; Herve, 2016 [173]).

These risk factors can lead to residual clinical soil in endoscopy channels and outer surfaces (i.e., distal end, elevator mechanism) after cleaning procedures (Visrodia, 2014 [369]; Ofstead, 2015 [235]; Ofstead, 2017 [238]; Ofstead, 2018a [237]; Alfa, 2014a [56]). Effective cleaning followed by routine sterilization of flexible endoscopes is preferred because of the significant public health risk. Sterilization of endoscopes can reduce this risk because of the greater margin of safety in the overkill process, and terminal sterilization provides a sterile packaged endoscope (Rutala and Weber, 2016a [279]; McCool et al., 2012 [209]; Wendorf et al., 2015 [375]; Rubin and Murthy, 2016 [273]; Smith et al., 2015 [294]). High-level disinfection is a multi-step process and is expected to be able to inactivate most pathogenic bacteria, viruses, and fungi, but may not reliably inactivate certain types of microorganisms, including bacterial spores.

Transition from high level disinfection to sterilization as the standard of care may be accelerated by identifying and addressing key technical and compatibility obstacles and defining priorities and key steps.

Contribution of reusable medical device manufacturer is essential (FDA 2015, updated 2017 [338]). Partnerships between sterilizer and medical device manufacturers are encouraged.

Although endoscopes play a vital role in the effective delivery of health care and offer patients many benefits, the risks associated with iatrogenic transmission via endoscopes continue to be of significant concern. Endoscope design complexity presents a substantial challenge to achieving consistent and effective processing. Although risk mitigation steps, such as inspection prior to every use, are detailed in manufacturers' instructions, these steps fail to account for the high-risk design elements, such as long, internal lumens and recessed spaces that either cannot be visualized or are difficult to visualize.

The process of improving patient safety in flexible endoscopy is multi-factorial, needing clear guidance on endoscope processing, effective training and competency verification of personnel, comprehensive quality control systems, validated methods for ensuring adequate processing, and designing processes with margins of safety that account for the level of risk associated with use of these devices (FDA, 2019 [337]). As part of this process, continued research, and partnership between endoscope, reprocessor and sterilizer manufacturers to support elevating the standard of endoscope processing from high-level disinfection to sterilization is encouraged.

Flexible and semi-rigid endoscope processing in health care facilities

1 Scope

This standard provides guidelines for point of use treatment, transporting, leak testing (where indicated), cleaning, packaging (where indicated), high-level disinfecting and/or sterilizing, storage, and quality control procedures of flexible gastrointestinal (GI) endoscopes, flexible bronchoscopes, flexible ear, nose, and throat endoscopes, flexible urology endoscopes, and other types of reusable flexible endoscopes used in procedural and surgical settings, and semi-rigid operative endoscopes (e.g., choledochoscopes) used in health care facilities. These guidelines are intended to provide comprehensive information and direction for health care personnel in the processing of these reusable devices and accessories to render them safe for patient use.

NOTE For purposes of this standard, “health care facilities” include, but are not limited to, hospitals, ambulatory surgery facilities, physicians' offices, cardiac catheterization laboratories, endoscopy suites and centers, respiratory therapy clinics, urology clinics, and other areas where reusable medical devices are processed, stored, and used.

1.1 Inclusions

This document specifically addresses:

a) functional and physical design criteria for endoscope processing areas;

b) education, training, competency verification, and other personnel considerations;

c) processing recommendations;

d) care and inspection of endoscopes;

e) maintenance of processing equipment;

f) facility risk management considerations;

g) quality control;

h) quality process improvement.

Definitions of terms, a bibliography, and informative annexes are also provided in this standard.

1.2 Exclusions

This standard does not cover:

a) the processing of rigid endoscopes (see ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities [17]; ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities [14]; and ANSI/AAMI ST41, Ethylene oxide sterilization in health care facilities: Safety and effectiveness) [12];

b) the processing of transesophageal echocardiogram (TEE) probes, or endocavity ultrasound probes;

c) specific construction and performance criteria for steam sterilizers (see ANSI/AAMI ST8, *Hospital steam sterilizers* [10], and ANSI/AAMI ST55, *Table-top steam sterilizers*) [13], ethylene oxide gas sterilizers (see

ANSI/AAMI ST24, *Automatic, general-purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities*) [11], rigid sterilization container systems (see ANSI/AAMI ST77, *Containment devices for reusable medical device sterilization*) [16], or rigid, protective organizing cases that require wrapping before sterilization (see ANSI/AAMI ST77); or

d) the processing of devices labeled for single use only and not intended to be processed by the healthcare facility prior to use.

NOTE For more information on the subjects excluded from the scope of this standard, and for additional background information on the inclusions, refer to the references listed in the Bibliography.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

3.1
automated endoscope reprocessor
AER
<endoscope washer–disinfector>
machines designed for the purpose of cleaning and/or disinfecting or liquid chemically sterilizing endoscopes and components.

Note to entry: The process can use a cleaning agent, and always uses a high-level disinfectant (HLD) or liquid chemical sterilant (LCS) solution.

3.2
bioburden
population of viable microorganisms on a product and/or a sterile barrier system

Note to entry: When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units (CFUs) per single item.

3.3
biofilm
accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (Donlan, 2002) [136]

Note to entry: Some microscopic organisms have the ability, when growing in water or water solutions or *in vivo* (e.g., the bloodstream), to adhere to a surface and then exude over themselves a polysaccharide matrix. The matrix contains cells, living and dead, as well as polysaccharide (sometimes referred to as extracellular polymeric substance), and prevents antimicrobial agents, such as sterilants, disinfectants, and antibiotics, from reaching the microbial cells.

3.4
biological indicators
BIs
test systems containing viable microorganisms providing a defined resistance to a specified sterilization process

Note 1 to entry: According to the FDA, “a biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of a known number of microorganisms, of known resistance to the mode of sterilization, in or on a carrier and enclosed in a protective package. Subsequent growth or failure of the microorganisms to grow under suitable conditions indicates the adequacy of sterilization.” [21 CFR 880.2800(a)(1)] [329]

Note 2 to entry: Biological indicators are intended to demonstrate whether or not the conditions were adequate to achieve sterilization. A negative Biological Indicator (BI) does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

Note 3 to entry: See ISO 11138-7 for information on the selection, use, and interpretation of biological indicators.

3.5
borescope
device used for visual inspection of areas that are inaccessible by other means

Note to entry: Some borescopes are equipped with cameras that provide still images or video of inaccessible areas within endoscope lumens.

3.6
case/cassette
sterilization containment device that consists of a lid and base tray that has perforations to allow the sterilant to penetrate and that is enclosed in a sterile barrier system suitable for specified sterilization method(s) to maintain sterility

3.7
certification
process by which a non-governmental agency or association certifies that an individual has met certain predetermined standards specified by that profession for specialty practice

3.8
challenge test pack
pack used in qualification, installation, and routine quality assurance testing of health care sterilizers

Note to entry: See also process challenge device.

3.9
chemical indicators
CIs
devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment

Note 1 to entry: ANSI/AAMI/ISO 11140-1:2014, *Sterilization of health care products—Chemical indicators—Part 1: General requirements* [2], defines six types of CIs and specifies performance requirements for them:

Type 1 (process indicators): chemical indicators intended for use with individual units (e.g., packs, containers) to indicate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units.
Type 2 (Bowie-Dick test indicators): chemical indicators intended for use in a specific test procedure (e.g., the Bowie-Dick test used to determine if air removal has been adequate in a steam sterilization process).
Type 3 (single critical process variable indicators): chemical indicators designed to react to one of the critical variables and intended to indicate exposure to a sterilization process at a stated value of the chosen variable.
Type 4 (multicritical process variable indicators): chemical indicators designed to react to two or more of the critical variables and intended to indicate exposure to a sterilization process at stated values of the chosen variables.
Type 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ANSI/AAMI/ISO 11138 series for BIs.
Type 6 (emulating indicators): chemical indicators designed to react to all critical variables of specified sterilization cycles, with the stated values having been generated from the critical variables of the specified sterilization process. ANSI/AAMI/ISO 11140-1 refers to these indicators as cycle verification indicators. [2]

Note 2 to entry: FDA recognition of chemical indicators is limited to Type 1 process indicators; Type 2 indicators for use with special tests; and Type 6 emulating indicators (ANSI/ AAMI/ISO 11140-1:2014) [2].

Note 3 to entry: The International Standards Organization published a revised version of ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, in 2014 [2]. The ISO document was adopted by the Association for the Advancement of Medical Instrumentation (AAMI) and subsequently approved as an American National Standard, ANSI/AAMI/ISO 11140-1:2014. A key change in the 2014 version of the standard is the use of the term “type” rather than the term “class” of chemical indicator. As chemical indicator manufacturers update their device labeling to reflect the new standard, there will be a transition period during which end-users will observe some chemical indicators labeled as “Class X” and others labeled with the new term “Type X” in the marketplace.

3.10
chemical monitoring device

non-traditional indicator or LCS/HLD concentration measurement method

3.11
cleaning
removal of contamination from an item to the extent necessary for further processing or for the intended use

Note to entry: In health care facilities, cleaning consists of the removal, usually with detergent and water, of adherent clinical soil (e.g., blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.

3.12
clinical soil
residues on medical instruments after patient use

3.13
competency
an expected level of performance that integrates knowledge, skills, abilities, and judgment.

Note to entry: Certification in reprocessing of endoscopes does not mitigate the need for orientation, ongoing education training/education and competency assessments (CDC, 2017 [108]).

3.14
competency verification
activity designed to substantiate or confirm the ability of an individual to successfully complete a particular skill, task, complex series of tasks, or behavior necessary to perform effectively

3.15
CQI
continuous quality improvement

3.16
critical device
device that is introduced directly into the bloodstream or which contacts a normally sterile tissue or body space during use

3.17
critical water
water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, deionization [DI], and reverse osmosis [RO] or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process

Note 1 to entry: This water is mainly used for the final rinse or for steam generation.

Note 2 to entry: See AAMI TIR34 [23] for specifications.

3.18
decontamination
process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard (CDC, 2008 [107])

3.19
decontamination area
area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items

3.20
education
knowledge, comprehension, and insight acquired by an individual after studying a specific subject

3.21
endoscope sheath
sterile, single-use protective barrier for various types of endoscopes, intended to cover the entire insertion tube of the endoscope and which might contain air, water, or suction channels but most often is single channel (FDA, 2000b) [340]

3.22
engineering controls
concept that, to the extent feasible, the work environment and the job itself are designed to eliminate or reduce exposure to hazards

3.23
ethylene oxide (EO) sterilization
validated process used to render a device free of viable microorganisms that utilizes ethylene oxide gas as the active sterilant

3.24
expiration date
date that is calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component and that defines its estimated useful life

3.25
expiration statement
statement, also known as a day-to-day expiration date, indicating that the contents of a package are sterile indefinitely unless the integrity of the package is compromised

3.26
exposure control plan
according to OSHA, “a written [plan] designed to eliminate employee exposure to bloodborne pathogens” (29 CFR 1910.1030(C)(1)) [231]

3.27
exposure time
period for which sterilization or high-level disinfection process parameters maintain their specific tolerances

Note to entry: In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature and pressure.

3.28
gaseous and vapor chemical sterilization
validated process employing gaseous and/or vapor chemical sterilants (e.g., ethylene oxide [EO], hydrogen peroxide, ozone)

3.29
high-level disinfectant
HLD
germicide that inactivates all microbial pathogens except for bacterial endospores when they are present in large numbers, when used according to labeling (Rutala, 1990 [280])

Note to entry: According to the FDA, an HLD is a liquid chemical sterilant (LCS) used for a shorter exposure time than that required to pass the AOAC International sporicidal activity test as a sterilant.

3.30
high-level disinfection
process that kills all microbial pathogens but not necessarily high numbers of bacterial spores

Note to entry: For a process that can be used for both liquid chemical sterilization and high-level disinfection, the contact time for high-level disinfection is shorter than that necessary for sterilization, under otherwise identical conditions.

3.31
high-risk endoscopes
endoscopes that have been associated with infectious outbreaks including those that are difficult to process and increase the risk of incomplete clearance of contaminating infectious organisms, including bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes, ureteroscopes, and others as determined by the facility

3.32
hydrogen peroxide sterilization
validated process used to render a device free of viable microorganisms that utilizes a formulation of vaporized hydrogen peroxide as the active sterilant and might or might not include a plasma phase to help break down hydrogen peroxide

3.33
hydrogen peroxide–ozone sterilization
validated process used to render a device free of viable microorganisms that utilizes a formulation of vaporized hydrogen peroxide–ozone as the active sterilant

3.34
iatrogenic
relating to illness caused by medical examination or treatment

3.35
inspect
to assess a medical device carefully and visually, typically to evaluate the condition or to discover any residual debris or damage, using the unaided eye, lighted magnification and/or a borescope

3.36
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

3.37
instrument air
medical gas that falls under the general requirements for medical gases as defined by NFPA 99, *Health care facilities code*) [216], is not respired, is compliant with ANSI/ISA S-7.0.01 (*Quality standard for instrument air*), and is filtered to 0.01 microns, free of liquids and hydrocarbon vapors, and dry to a dew point of -40 °F (-40 °C)

{SOURCE: ANSI/AAMI ST79:2017, 2.56} [17]

3.38
labeling
any literature, including instructions for use, provided with a device as well as all advertising claims published by the manufacturer (21 CFR 801) [328]

3.39
liquid chemical sterilant
LCS
solution of a chemical that passes the AOAC Sporicidal Activity Test as a sterilant

3.40
liquid chemical sterilant processing system
LCSPS
specific category of AER that uses a liquid chemical sterilant to achieve liquid chemical sterilization of the medical device load, which is frequently an endoscope and its accessories

3.41
liquid-resistant material
material that inhibits the penetration of liquids

Note to entry: According to ANSI/AAMI PB70 [9], a liquid-resistant material would be defined as a Level 1, 2, or 3 barrier material.

3.42
lot control number
<load control number>
numbers, letters, or a combination of both, by which a particular group of products can be traced to a particular manufacturing or sterilization operation

3.43
magnification
use of a tool to enhance the visual inspection of a device by enlarging the image

3.44
manufacturer's written instructions for use
IFU
written directions developed, validated, and provided by the manufacturer of a device that provide instructions for operation, safe and effective processing

3.45
medical device
instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
- investigation, replacement, or modification of the anatomy or of a physiological process; or
- control of conception; and

does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

3.46
minimum effective concentration
MEC
“Minimum concentration of a liquid chemical sterilant/high-level disinfectant that achieves the claimed microbicidal activity; the MEC is determined by dose response testing.” (FDA, 2000a) [339]

3.47
minimum recommended concentration
MRC
minimum concentration at which the manufacturer of a liquid chemical sterilant or high-level disinfectant tested the product and validated its performance

Note to entry: The term “minimum effective concentration” (MEC) is sometimes used interchangeably with “minimum recommended concentration.” The MRC is not necessarily an MEC as determined by dose response testing. Some older IFU may state MEC, not MRC.

3.48
occupational exposure
contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment

Note 1 to entry: Occupational exposure to hazardous materials, including chemical and biological agents and potentially infectious materials, is regulated by OSHA (29 CFR Part 1910).

Note 2 to entry: The OSHA bloodborne pathogens regulation (29 CFR 1910.1030 [231]) specifically defines occupational exposure as “reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.”

3.49
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

3.50
OSHA
United States Department of Labor Occupational Safety and Health Administration

3.51
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

3.52
personal protective equipment
PPE
according to OSHA, “specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts, or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment” (29 CFR 1910.1030) [231]

3.53
point of use treatment
the collective activities that the user of a medical device performs at the point of use (where the procedure using the endoscope was performed) to prepare it for processing, occurring immediately after patient use and including precleaning (to prevent biofilm formation and drying of soil), disconnecting accessories, preparing handoff communication, and preparing the endoscope for transport to the decontamination by attaching required caps and placing in an appropriately-labeled container

Note to entry: For purposes of this standard, precleaning and point of use care have the same meaning as point of use treatment.

3.54
preventive maintenance
routine servicing of equipment for the purpose of maintaining it in good working condition

3.55
process challenge device
PCD
item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

Note to entry: For purposes of this standard, a PCD is a challenge test pack containing a BI or a BI and a CI. See AAMI TIR31 [22].

3.56
processing
process carried out on a device to allow its subsequent safe use, which can include cleaning, disinfection, sterilization, and related procedures

3.57
processing area
area of a health care facility where devices are decontaminated, cleaned, inspected, assembled into trays, and prepared for high-level disinfection and/or sterilization

3.58
pseudoinfection
laboratory evidence of the presence or activity of pathogenic microorganisms in the absence of infection, which can result from colonization of the site without infection, contamination of the specimen, or laboratory error or misinterpretation yielding a false-positive test result for an infectious disease

3.59
reprocessing
see *processing* (3.56)

3.60
reusable containment device
reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization

3.61
reusable medical device
device intended for repeated use on different patients, with decontamination and other processing between uses

Note to entry: Examples include surgical instruments, endoscopes, basins, and electromedical equipment.

3.62
rigid sterilization container system
sterilization containment device designed to hold medical devices for sterilization, storage, transportation, and aseptic presentation of contents

Note to entry: The system generally consists of a bottom or base with carrying handles and a lid that is secured to the base by means of a latching mechanism. A basket or tray to hold instruments or other items to be sterilized is placed inside. A filter or valve system is incorporated into the lid and/or base to provide for air evacuation and sterilant penetration during the sterilization cycle and to act as a barrier to microorganisms during storage, handling, and transport.

3.63
safety data sheet
SDS
previously referred to as MSDS (material safety data sheet), this document is required to be provided by the manufacturer of chemicals used in the workplace, such as disinfectants

3.64
semi-critical device
device that contacts intact mucous membranes or non-intact skin but does not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body

3.65
shelf life
when the term is used with respect to a processed or sterilized medical device, the period of time during which the item is considered safe to use

3.66
solid container
container that maintains its shape is puncture resistant and is intended to protect its contents

3.67
solution test strip
device used to monitor the concentration of the active ingredient(s) in a liquid chemical sterilant/high-level disinfectant solution and determine if the MRC or MEC is acceptable for effective use

3.68
Spaulding classification
strategy for determining the level of processing needed for contaminated medical devices, which is comprised of a system that classifies a medical device as critical, semi-critical, or noncritical based on risk to patient safety from contamination on a device and establishes three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and noncritical)

3.69
spore test strip
test system containing a known number of bacterial spores (at least 10^5 per strip) of known resistance to a liquid chemical sterilant and used in a defined liquid chemical sterilant processing system

3.70
standard precautions
"The minimum infection prevention measures that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. These evidence-based practices are designed to both protect healthcare personnel and prevent the spread of infections among patients. Standard Precautions replaces earlier CDC guidance relating to Universal Precautions and Body Substance Isolation. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, facemasks), depending on the anticipated exposure, 3) respiratory hygiene and cough etiquette, 4) safe injection practices, and 5) safe handling of potentially contaminated equipment or surfaces in the patient environment." (CDC, 2011) [104]

3.71
steam sterilization
sterilization process that uses saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent

3.72
sterile
free from viable microorganisms

3.73
sterile processing area
area within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility

3.74
sterilization
validated process used to render a product free from viable microorganisms

3.75
sterilization cycle
defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber

3.76
sterilizer
apparatus used to sterilize medical devices, equipment, and supplies by direct exposure to the sterilizing agent

3.77
terminal cleaning
thorough environmental cleaning that includes, but is not limited to walls, floors, horizontal surfaces, movable equipment, non-movable equipment, utility sinks, hand hygiene sinks, air vents, storage cabinets and racks

3.78
terminal sterilization
process whereby product is sterilized within its sterile barrier system that permits storage for use at a later time

3.79
training
process or organized activity designed to help an individual attain the necessary skill or behavior required to perform, or improve an individual's performance of, a particular task

Note to entry: The specific goals of training are to improve capability, capacity, productivity, and performance.

3.80
user verification
documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met

3.81
utility water
water that comes from the tap for flushing, washing, or rinsing

Note to entry: See AAMI TIR34 [23] for specifications.

3.82
validation
documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

Note to entry: Validation is performed by the manufacturer.

4 Design of endoscope processing area

4.1 General considerations

The processing area should be physically separated from the patient care areas and procedure rooms. The processing area should be designated for processing only and designed to allow for the unidirectional flow of devices from the receipt of new and/or used endoscopes to storage prior to next patient use, including:

a) receipt of devices, leak testing;

b) cleaning (decontamination);

c) inspection;

d) storage; and

e) disinfection and drying or packaging and sterilization.

In all cases, facilities should ensure a unidirectional flow from dirty to clean; conduct an analysis to identify risks; and minimize these risks by policies, procedures, education, and training of processing personnel.

An area should be defined at the incoming end of the unidirectional flow process for the receipt and temporary holding of devices before cleaning. If a lift is used for transport, it should be dedicated to the transport of either clean or contaminated items only (see 6.3.2).

The design of the endoscope processing area should facilitate the highest level of infection prevention and patient and employee safety. An area designed with environmental needs such as solid, nonporous horizontal surfaces, lighting, and utility support of electricity should be provided in areas used for endoscope processing. When designing an endoscope processing area based on applicable regulations, considerations include, but are not limited to:

a) ability of work surfaces to withstand frequent cleaning and disinfection;

b) workflow;

c) patient volume (current and anticipated);

d) number and types of endoscopes and equipment;

e) quantity and types of processing equipment (e.g., sterilizers, AERs, washer-disinfectors);

f) scope and equipment storage requirements;

g) supply and chemical storage requirements;

h) number of people anticipated to be working in the area;

i) traffic flow;

j) required utilities (e.g., instrument air with a regulator, if necessary, source of water of appropriate quality, lighting, electricity, data drops, heating, ventilation, air conditioning (HVAC), negative air flow and adequate air exchange rates, suction capabilities);

k) ergonomics and human factors;

l) clean space required for visual inspection and cleaning verification tests; and

m) area for employees to take breaks as food and drink are not permitted in the endoscope processing area.

4.2 Workflow

4.2.1 General considerations

Workflow should be unidirectional from the decontamination area to the clean area and then to the storage area. Workflow patterns should be designed to contain contaminants, prevent damage to endoscopes, and minimize employee exposure to pathogens and toxic chemicals.

Ergonomic factors affecting worker safety and comfort should be considered when designing work areas. For example:

— Counters, sinks and work surfaces should be:

- height-adjustable or positioned at heights that accommodate the average height of employees and the tasks to be performed at each location; and
- sufficient to accommodate the endoscope length.

— Anti-fatigue mats should be:

- used in areas where prolonged standing is required; and
- constructed of materials capable of withstanding frequent cleaning.

Work area design also should allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. A pass-through window at counter height between the decontamination area and clean processing area is recommended.

Rationale: Adherence to these functional design recommendations can help contain potential contaminants within the processing area and prevent cross-contamination or recontamination. Designing the area to facilitate efficient workflow and to provide adequate space for necessary equipment can enhance efficiency and reduce the potential for cross-contamination. Considering ergonomic factors during the design phase can help prevent worker injury. A pass-through window that can be closed is convenient for devices that have been manually decontaminated to be passed over to the clean side for processing. Having a window that can be closed maintains the air pressure requirements as well as maintaining the integrity of the clean side.

4.2.2 Physical separation

Facilities should have two separate rooms for processing endoscopes. Until such time (major renovations or new construction) that two separate processing rooms can be provided, strict unidirectional processing procedures should be in place to reduce risks of cross-contamination. After cleaning, PPE should be changed, and hand hygiene performed before any disinfection or sterilization activities. The endoscope processing area should also include a designated drying area, when applicable, to dry the device with forced instrument air prior to patient use, storage, or in preparation for packaging and terminal sterilization.

Adequate space shall be provided to allow for the manual cleaning and rinsing of devices during decontamination. It is optimal that the manual cleaning area is physically separated by walls or partitions in a two-room configuration to control contaminants generated during manual cleaning. Doors that open in the direction of the one-way workflow and closeable pass-through windows separating the decontamination area from the adjoining disinfection/sterilization area should remain closed when not in active use. An endoscopy processing room with a one-room design should provide a minimum of 4 feet between the decontamination area and the clean work area and either a separating wall or a barrier that extends a minimum of 4 feet above the sink rim to separate soiled work areas from clean work areas (FGI, 2018 [146]; AORN, 2018e [39]).

An area should be defined for disinfection/sterilization that is separate from the manual cleaning/processing area. For manual processing, this area should include a designated area for the immersion of the device for disinfection followed by rinsing in accordance with the disinfectant manufacturer's written IFU. For automated processing, the AER, washer–disinfector, or sterilizer forms an essential barrier between the dirty and clean areas of the processing area. Sufficient space and utilities for the units should be provided along with adequate space for storage of chemicals near the AER. Strict unidirectional processing procedures should be in place to reduce risks of cross-contamination following an antimicrobial process. A pass-through AER is another option to fulfill these requirements. This should include a designated drying area to dry the device prior to patient use, storage, or in preparation for packaging and gaseous sterilization.

Flexible endoscopes should be stored in a clean, secure location but not within the endoscopy procedure room (AORN, 2018e [39]. Physical separation of this area from the main processing area is preferred to minimize risk of cross-contamination during storage.

Rationale: Physical enclosure of the decontamination area is necessary because contaminated aerosols, droplets, and dust particles can be carried from "dirty" to "clean" areas by air currents. Separating "clean" and "dirty" areas helps

prevent environmental contamination. Segregation of contaminated items from items being removed from mechanical processing equipment (e.g., AERs, storage equipment) can help protect processed flexible and semi-rigid endoscopes from recontamination. A study (Johnston et al., 2019 [185]) determined that contaminants during a gastroenterology procedure could travel significant distances in the procedure room, contaminating items hanging on the wall, not used during the procedure.

4.2.3 Traffic control

Traffic in the processing area should be restricted to authorized personnel wearing appropriate attire. Criteria for authorized entry, movement, and attire within the decontamination and clean areas should be specified in the policies and procedures of the facility.

It might be necessary for visitors to enter restricted areas. Visitors should comply with facility policies and procedures. The responsibility and authority for enforcing traffic control policies and procedures should be specified in the facility policies and procedures, as should methods of compliance.

Rationale: Personnel and visitors can carry microorganisms into the processing areas, thus increasing the potential for environmental contamination in these areas. It is also important to protect personnel and visitors from the microorganisms present on contaminated items being processed and potentially hazardous chemicals used in the decontamination area.

4.3 Physical facilities

4.3.1 General space requirements

The needs of the facility should determine the size of the processing areas. Sufficient space should be provided for each function and include dedicated storage space.

Considerations for space requirements include:

a) operational systems;

b) equipment; and

c) the anticipated workload in each functional work area.

Space requirements should be based on:

a) the volume of work anticipated;

b) the amount of product that will be routinely stored;

c) disposal needs; and

d) the degree of mechanization, the product mix (e.g., reusables vs. disposables), and the storage methods used, which might change over time.

There should be adequate space for:

a) maneuvering, queueing, and unloading carts or other transportation systems at times of average daily peak workload; and

b) record-keeping, either manual or computerized.

4.3.1.1 Space requirements in the decontamination area

In the decontamination area, sufficient space should be allocated for:

a) decontamination sink for manual cleaning;

b) workspace to perform inspection by unaided eye and/or use of tools such as lighted magnification and/or a borescope;

c) cleaning verification/equipment counterspace;

d) trash bins;

e) laundry bins;

f) separate sink designated for hand hygiene;

g) an emergency eyewash station that is separate from the decontamination sink;

h) storage of cleaning chemicals;

i) storage of cleaning implements;

j) storage of PPE;

k) sink and/or counterspace for leak testing;

l) leak testing equipment;

m) automated flushing systems;

n) suction machines;

o) drying (instrument air, adapters, connectors);

p) servicing of the equipment;

q) water treatment for critical water; and

r) documentation manual or electronic and method to dispose of patient labels.

NOTE It is permissible to combine handwashing sink and emergency eyewash station.

According to NFPA 99, *Health care facility cod*e [216], a separate vacuum system for performing suction in processing is needed.

Allocate sufficient space for filtration system and utilities for the AER. Adequate space for storage of detergents and disinfectants near the AER should also be considered.

4.3.1.2 Space requirements in the preparation area

The preparation area should be adjacent to the area used for sterilization or disinfection. Sufficient space should be allocated for:

a) inspection and inspection equipment such as lighted magnification and/or a borescope;

b) workspace to fully lay out an endoscope for inspection;

c) instrument air, adaptors, and connectors;

d) documentation manual or electronic which may include computer, printer, and label maker;

e) storage for all packaging supplies (i.e., quality monitors, tape wrappers); and

f) separate sink designated for hand hygiene (i.e., sink with soap and paper towels).

4.3.1.3 Space requirements for terminal sterilization

Sufficient space should be designed for:

a) the appropriate sterilization equipment;

b) the capacity of the sterilizer (i.e., number of endoscopes per sterilization cycle) combined with the cycle time of the sterilization process to accurately determine the number of sterilizers required in the space to meet turnaround expectations;

c) space for sterilization supplies (e.g., BIs, CIs, test packs, pouches, wraps, rigid containment system, etc.); and

d) servicing area for sterilizer.

4.3.1.4 Space requirements for manual high-level disinfection or manual liquid chemical sterilization

If a facility anticipates using manual high-level disinfection or manual liquid chemical sterilization, sufficient space should be allocated in the clean area for:

a) manual containers placed close to a sink (AORN, 2019a [35]);

b) separate sinks for rinsing;

c) ventilation hoods, if needed;

d) storage of HLD chemicals, sterilant chemicals, spill kits, PPE, instrument air, alcohol, adapters, connectors, and filters;

e) water treatment for critical water;

f) drying;

g) documentation;

h) sink designated for hand hygiene; and

i) emergency eye wash station.

NOTE It is permissible to combine handwashing sink and emergency eyewash station.

Rationale: Space requirements can vary significantly depending upon the specific processing needs of the facility and are often underestimated during the planning process. Adequate space is needed for effective and safe endoscope processing. Mechanical processing improves effectiveness, increases efficiency, minimizes personnel exposure to biohazardous materials and chemicals, and can be more successfully monitored for quality and consistency.

4.3.1.5 Space requirements for automated high-level disinfection or liquid chemical sterilization

If automated high-level disinfection is anticipated, sufficient space should be designed for:

a) the appropriate high-level disinfection or liquid chemical sterilization equipment;

b) the capacity requirements;

c) filtration system and utilities for the AER;

d) servicing area for automated equipment;

e) storage of LCS/HLD chemicals, spill kits, PPE instrument air, alcohol, connectors, or filters;

f) drying; and

g) documentation.

4.3.2 Sinks and accessories

Processing areas should have dedicated plumbing and drains that meet the needs of the facility for volume and capacity.

NOTE Some jurisdictions have regulations that apply to plumbing. Uniform Plumbing Code (UPC) can be useful to reference.

Provisions for chemical disposal should be integrated into the design of the decontamination space as described in the manufacturer's written IFU and in accordance with local, state, and federal regulations.

Sinks should be deep enough to allow complete immersion of the endoscope to minimize aerosolization. The size of the sink should be adequate (i.e., a minimum of 16 inches x 30 inches) to ensure that the endoscope can be positioned without tight coiling. Sinks should be height-adjustable so that personnel do not have to bend over to clean endoscopes. An ideal decontamination sink is height-adjustable, approximately 36 inches (91 centimeters [cm]) from the floor and 8 to 10 inches (20 to 25 cm) deep, enabling a person of average size to work comfortably without undue strain on the back; foot stools should be readily available to accommodate shorter personnel.

At a minimum, two sinks or one sink with two separate basins should be used. Consideration should be given for additional space for delayed processing protocol. One sink or sink basin should be designated for leak testing and manual cleaning and the other only for rinsing. Optimally, three sinks or one sink with three separate basins should be used, with each function in a separate sink or basin.

The sink or sinks should have faucets or manifold systems, adapters that attach to the faucet, or other accessories that facilitate the flushing of instruments with lumens. Sinks should have attached solid counters or adjacent work surfaces on which to place the endoscope while attaching it to the leak tester, detach and separate removable components, and to inspect the endoscope for physical damage and cleaning effectiveness.

Lighting of the recommended illuminance should be placed above the sink and counter area so that personnel can adequately perform inspection activities as the endoscope is processed (see 4.3.8 and Table 1). A lighted magnifier should be available for inspection.

Instrument air along with a pressure regulator should be provided in the processing area. Instrument air with an upper limit of pressure as described in the endoscope manufacturer's written IFU should be provided at the sink for flushing lumened devices.

Critical water for final rinsing should be provided in necessary locations (see 4.3.11 and AAMI TIR34 [23]).

A hand hygiene sink, which is separate from utility sinks, should be located in the decontamination area (see also 4.3.9).

Rationale: The design and location of sinks can facilitate cleaning as well as employee safety. Tight coiling of the endoscope could damage components, including image or light bundles, internal channels, tubes, and/or angulation wires. Height-adjustable sinks enable personnel to avoid bending over to perform cleaning. Sinks located too high or too low increase the risk of back injury or strain. Current medical technology could require complex equipment and systems to inspect, maintain, or verify device performance.

4.3.3 Electrical systems

Electrical systems should be designed to allow for the safe and effective operation of the equipment (e.g., cleaning equipment, sterilization equipment, computers, telephones, lighting) used in the processing area. The emergency power service of the facility should be extended to include sterilization and processing equipment. The electrical engineers involved in the design processes should be informed of the work performed in the processing area and should be provided a detailed list of specific equipment used and installation specification specific to this equipment. Electric engineers should collaborate with managerial or other designated personnel when determining electrical system requirements. For some equipment, uninterruptible power sources are recommended. The equipment manufacturer's

installation and site-planning requirements should be reviewed and met. The need for data drops/lines should be reviewed.

Rationale: The complexity of processing and sterilization technologies, as well as patient and personnel safety, requires adequate, safe, and reliable electrical and data service.

4.3.4 Floors and walls

Floors in the processing areas should be level (i.e., should have no ridges or bumps), non-slip, monolithic or joint-free, and constructed of materials that will withstand daily or more frequent wet cleaning and the application of cleaning and disinfecting agents. Carpet should not be used in the processing areas.

Walls should be constructed of materials capable of withstanding frequent cleaning. Wall protectors should be installed at the level of possible cart impacts.

Materials used in floors and walls should be of a non-particulate or non-fiber-shedding composition.

Rationale: Uneven floors could make it difficult for personnel to push carts; also, uneven floors can cause items on carts to shake and even fall off the cart. Joints and crevices in floors could harbor microorganisms. Some sterilizer carts have blunt ends that can nick walls, eventually removing the cover material and exposing porous fibers that can shed into the environment and prevent effective cleaning.

4.3.5 Ceilings

Processing area ceilings should:

a) be constructed to create a flush surface with recessed, enclosed fixtures;

b) enclose pipes and duct work above work areas;

c) be constructed of materials that are not of a particulate- or fiber-shedding composition; and

d) be durable, smooth, and cleanable.

Rationale: A finished ceiling with enclosed fixtures limits condensation, dust accumulation, and other possible sources of contamination.

4.3.6 Doors

A door should provide access to the decontamination area from the corridor, and any door that provides access to the decontamination area must have a hazard warning sign (29 CFR 1910.1030) [231].

Doors in the processing area should be made of a durable, nonporous material that can withstand frequent bumping from back tables and carts and that can be cleaned and disinfected frequently. Doors should not have thresholds and should open easily following the one-way directional workflow. Doors should be hands-free, as personnel might be holding endoscopes with both hands.

Rationale: Carts are frequently pushed from one area to the next. Doors require frequent cleaning. It can be difficult for personnel to pull open a door and push a cart through it. The frequent bumping of doors by carts might damage the door surface and expose porous materials that could harbor bacteria and other contaminants and are difficult to clean. Bumping against a threshold can cause carts to spill and might necessitate picking up the cart to traverse the threshold.

4.3.7 Heating, ventilation, and air conditioning (HVAC) operating parameters

Requirements for HVAC in the endoscope processing area should conform with the specifications of ANSI/ASHRAE/ASHE 170 [34] that were in effect when the HVAC system was initially installed or last upgraded. The health care facility should establish and implement systematic processes for monitoring HVAC performance parameters

and a mechanism for identifying and resolving variances within the rooms throughout the facility where processing occurs.

Facility engineering personnel or designated responsible personnel should establish policies and procedures for monitoring and maintaining HVAC parameters within the processing areas. Procedures should include maintaining records of monitoring results that are retrievable either from a central system or a local log.

If a variance in the HVAC parameters occurs, processing personnel in combination with a multidisciplinary team (e.g., facility engineer, infection preventionist, risk manager, endoscopy personnel, perioperative personnel, sterile processing manager or other designated personnel) should conduct a risk assessment. The processing department is defined by ANSI/ASHRAE/ASHE 170 [34] as a critical area.

Neither fixed nor portable fans should be permitted in the processing area, with the exceptions of exhaust fans on ventilation systems and installed and operated fume control hoods.

See also Annex A.

Rationale: The effect of the HVAC system parameters falling out of range is variable. A risk assessment provides necessary information to guide appropriate response measures. A small variance for a short period of time as defined in the risk assessment might not be of clinical concern, whereas a large variance for a longer period could have clinical significance. A risk assessment provides necessary information to guide appropriate response measures.

4.3.8 Lighting

Adequate lighting of work surfaces should be provided in accordance with the engineering practices and recommendations of the Illuminating Engineering Society of North America (IES) for minimum levels of illuminance for various categories of work environments.

The three levels of lighting for each category were calculated on the basis of the following factors:

1) the illumination needed varies from person to person, and with age, and so adequate illumination should be provided for all employees;

2) the importance of speed or accuracy of the work done in the area (the greater the importance of speed or accuracy, the more illuminance needed); and

3) the amount of light reflection in the work area (lighter colors reflect light; darker colors absorb light; the greater the reflectance, the less illuminance required).

The correct illuminance for each workspace within the processing area should be determined (see 4.3.2 and Table 1). Generally, all functions performed within a processing area require detailed and accurate inspection. Ancillary lighting should be considered for areas where instruments are manually cleaned and inspected. Lighting fixtures should be selected and mounted in positions that focus the light in front of the employee so that they are not working in their own shadows.

Table 1—IES-recommended illuminance levels for work environments*

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
Detailed inspection	1,000 lux (100 foot-candles)	1,500 lux (150 foot-candles)	2,000 lux (200 foot-candles)
Sink areas	500 lux (50 foot-candles)	750 lux (75 foot-candles)	1,000 lux (100 foot-candles)
General work areas	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)
Processed storage	200 lux (20 foot-candles)	300 lux (30 foot-candles)	500 lux (50 foot-candles)

*Source: Illuminating Engineering Society of North America (IES), Rea, 1993 [263]
Lights and other fixtures should be recessed and sealed to prevent the accumulation of dust or soil and to facilitate cleaning.

Rationale: Adequate lighting is essential to the performance of decontamination, preparation, inspection, and other processing tasks. Dust on lighting fixtures can act as a carrier of microorganisms.

4.3.9 Hand hygiene facilities

Hand hygiene facilities (i.e., sink, soap dispenser, towel dispenser, or alcohol-based hand rub dispensers) should be conveniently located and designed to allow good hand hygiene practices. The hand hygiene sink should be separate from the sink used to process endoscopes (AORN, 2018e [39]). Hand hygiene facilities should be located in or near all areas where endoscopes and other devices are decontaminated and in the clean area where endoscopes are high-level disinfected or sterilized. The installation of hands-free equipment (e.g., foot controls, electronic sensors) for use with sinks, towel dispensers, and soap dispensers should be considered during the design of new facilities or existing facilities under renovation. If electronic sensors are used, there should be a backup system for operation during power outages.

State regulations might dictate when and where alcohol-based hand rubs may be used and placed within the facility. The health department of the particular state should be consulted for specific regulations.

Rationale: Conveniently located hand hygiene facilities and alcohol-based hand rub dispensers help to promote hand hygiene and increase compliance with hand hygiene policies and procedures. Handwashing in the sinks used for endoscope cleaning could leave handwashing soap and bacteria on the endoscopes or contaminate personnel's hands (AORN, 2018e [39]). The use of alcohol-based, waterless hand hygiene agents is an effective means of hand decontamination when hands are not visibly soiled. Hands-free equipment helps personnel avoid touching faucet handles, soap dispensers, or towel dispensers, and might help to decrease microorganism transfer between patients, personnel, and inanimate objects. Some electronic sinks and towel dispensers operate only by the use of electricity and cannot function if the electrical power is off; a backup power system for hands-free equipment will ensure its continued operation.

4.3.10 Emergency eyewash/shower equipment

Suitable eyewash units must be available for immediate emergency use in all places where chemicals are used (29 CFR 1910.151) [228]. The American National Standards Institute (ANSI) has established minimum performance criteria for eyewash units (ANSI Z358.1 [32]). ANSI Z358.1 requires that eyewash units provide a minimum of 0.4 gallons per minute continuously for at least 15-minutes, that they be designed to flush both eyes simultaneously, and that they have a "hands-free, stay open" feature once activated. Under the ANSI standard, drench hoses or eyewash bottles are not acceptable emergency eyewash units.

Eyewash stations should be located:

a) so that travel time is no greater than 10 seconds from the location of chemical use or storage, or immediately next to or adjoining the area of chemical use or storage, if the chemical is caustic or a strong acid;

b) on the same level as the hazard with the path of travel free of obstructions (e.g., doors) that may inhibit immediate use of the eyewash station (ANSI Z358.1 [32]); and

c) in an area that does not require flushing of the eyes in the decontamination sink.

It is prudent to consider the stress and potentially compromised vision of the person and the availability of assistive personnel in the immediate area when determining the location of eyewash stations (ANSI Z358.1 [32]).
For a strong acid or strong caustic, the eyewash unit should be immediately adjacent to the hazard. The eyewash facilities should be identified with a highly visible sign and should be maintained in accordance with the manufacturer's written IFU. Before attempting to implement ANSI Z358.1, health care personnel should consult the standard to familiarize themselves with all its provisions [32].
Plumbed eyewashes/facewashes and showers should be activated weekly for a period long enough to verify operation and ensure that the flushing solution is available. When activating plumbed eyewashes, eye/facewashes, and showers,

personnel should also verify that they are providing lukewarm, tepid water (between 15 °C and 43 °C [60 °F and 110 °F]) (ANSI Z358.1 [32]). Routine testing should be documented.

Rationale: Many chemicals are classified as eye irritants. Eye contact with such chemicals can cause moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva.

The availability of eyewash units for immediate emergency use is required by OSHA. Maintenance of eyewash units is necessary to ensure adequate performance and to prevent contamination.

See Annex H. See also OSHA's Eye and Face Protection Standard (29 CFR 1910.133) [227], OSHA's Medical and First Aid Standard (29 CFR 1910.151) [228], and ANSI Z358.1 [32].

4.3.11 Water quality

Water quality is an important consideration in all stages of endoscope processing. It is important that the water quality that is identified in the manufacturer's written IFU is used during each stage of endoscope processing. To ensure that the correct water quality is used in each stage of processing, the user should review the manufacturers' written IFU for all equipment and supplies used, including:

a) endoscope and accessories;

b) AER; and

c) processing chemicals used.

Using the correct water quality helps to prolong the life of medical devices, facilitates their effective functioning, and, importantly, reduces the risk of medical device contamination.

The health care facility should monitor and control the water supply quality to endoscope processing sinks and equipment.

Major repairs of or changes to the water utility system should be treated as major repairs to the endoscope processing equipment (e.g., AERs), and equipment qualification testing should be performed before use.

Water quality evaluation should be conducted on installation of water-consuming equipment or the water supply, after repairs to water-consuming equipment or the water supply, after modification of water routing infrastructure, and during investigation of endoscope processing cycle failures.

See AAMI TIR34 [23].

5 Environmental cleaning

A multidisciplinary team should:

a) define roles and responsibilities for environmental cleaning;

b) select cleaning chemicals, materials, tools, and equipment for use in the endoscope processing setting;

c) establish cleaning frequencies for high-touch objects and surfaces (e.g., decontamination area work surfaces and sinks);

d) establish cleaning frequencies for all other surfaces including, but not limited to, storage shelves, endoscope storage cabinets, and similar objects;

e) establish terminal cleaning frequency for endoscope processing areas, at a minimum daily if the space is used and more often as needed (e.g., large biohazardous spill, known MDRO contamination of the environment); and

f) define an area outside of the processing area where food and beverage are permitted.

Cleaning logs should be maintained for the cleaning of the endoscope storage cabinet.

Environmental cleaning verification tools such as ultraviolet light visible markers, protein tests and ATP bioluminescence tests can be used to measure the adequacy of environmental cleaning. Environmental cleaning and disinfection procedures should be performed routinely or as needed in areas used for any aspect of decontamination, preparation, high-level disinfection, or sterilization. Contaminated work surfaces shall be decontaminated after completion of procedures, immediately or as soon as feasible when surfaces are overtly contaminated, or after any spill of blood or other potentially infectious material. Floors and horizontal work surfaces should be cleaned and disinfected at least daily. Other surfaces, such as walls, storage shelves, endoscope storage cabinets, and registers and duct diffusers, should be cleaned and disinfected on a regularly scheduled basis and more often if needed (AORN, 2018e [63]). Stained ceiling tiles should be replaced, and any leaks causing the stains should be repaired. There should not be any rust in the processing area. If rust is identified, it should be removed, and the cause remediated. A cleaning schedule should be established and followed for lighting fixtures or covers, based on a facility needs assessment to reduce the collection of dust particles and other potential contaminants.

Care should be taken to avoid contaminating patient-ready devices such as endoscopes or compromising the integrity of packaging during cleaning. Special attention should be paid to the sequence of cleaning to avoid transferring contaminants from “dirty” to “clean” areas and surfaces. It is good practice to provide separate storage areas for environmental cleaning supplies for the decontamination and clean areas. If environmental cleaning is contracted, written policy and procedures, IFU for products that are used, and other support information should be provided to the contractor.

Rationale: Cleaning removes soil and reduces environmental contaminants, thus reducing the risk of transmission of microorganisms. Food and beverage contaminate the processing area as well as the items being processed. The OSHA Bloodborne pathogen regulation forbids food and drink in the decontamination room (29 CFR 1910.1030) [231]. Measurement with cleaning verification tools provides a mechanism for feedback to improve the thoroughness of cleaning.

6 Personnel

6.1 General considerations

This section provides guidelines for policies and procedures related to the processing areas, as well as processing time requirements, education, training, and competency verification, and criteria for hand hygiene, immunizations, attire, and PPE for processing personnel. Studies have shown that most endoscope reprocessing technicians are under pressure to complete steps rapidly, and some acknowledge skipping steps to save time (Ofstead, 2010 [245]; Ofstead, 2019a [240]). Non-adherence to recommended steps has been documented in several studies where personnel reported cutting corners to save time (Ofstead, 2018a [237]; Ofstead, 2018b [242]). A multisite study found that completing all of the reprocessing steps required at least 90-minutes (Ofstead, 2019b [241]). Institutions should ensure that reprocessing personnel are provided sufficient time to complete steps in accordance with regulations, standards, guidelines, and manufacturer IFU.

6.2 Policies and procedures

Policies and procedures for endoscope processing (see 13.2), which include processes for monitoring adherence to the policies and procedures and a chain of accountability, should include guidelines for

a) delineating procedures for processing of endoscopes and endoscope accessories;

b) confirming that current versions of the manufacturers’ written IFU for the endoscope models, processing equipment, sterilizers, and all other devices are readily available to processing personnel;

c) confirming that facility processing procedures are consistent with the written IFU of the manufacturers of the endoscopes, processing systems, and accessories and consumables used (see Section 15); and

d) verifying processing personnel competency and consistent compliance with processing procedures.

Policies and procedures should be disseminated and readily available and used by all processing personnel. Managerial or other designated individuals should verify that processing personnel know the location of and can access facility policies and procedures. Processing personnel should inform manufacturers, as well as the FDA if applicable, if the IFU seems unclear or inadequate or are unable to be performed due to technical incompatibilities.

Policies and procedures should be reviewed by a multidisciplinary group (e.g., personnel representing GI, sterile processing, operating room, infection prevention and control, risk management, etc., as applicable to the facility) and updated at regular intervals established by the health care facility and/or local regulations.

Policies and procedures should be developed for the protection of processing personnel. These policies and procedures should include safety measures to protect personnel from exposure to pathogens and chemicals. In addition, policies and procedures should detail the exposure control plan. All policies and procedures designed for personnel protection should be developed in collaboration with the organization's infection prevention and employee/occupational health personnel.

NOTE Exposures to bloodborne diseases should be handled in accordance with OSHA regulations and current Centers for Disease Control and Prevention (CDC) recommendations.

Rationale: The protection of patients, employees, and other individuals in the health care facility depends on the implementation of policies and procedures designed to reduce the risk of exposure to potentially pathogenic microorganisms.

6.3 Education, training, and competency verification

6.3.1 General considerations

All personnel performing endoscope processing shall complete formal training and competency verification in all aspects of endoscope processing prior to first assignment to perform these tasks independently. All personnel performing processing of endoscopes should be certified in flexible endoscope processing within two years of employment and should maintain that certification throughout their employment.

NOTE Information concerning education, training, and/or certification of endoscopy technicians with processing duties, sterile processing managers, and technicians can be obtained from the Certification Board of Sterile Processing and Distribution (CBSPD) (www.cbspd.net), the Healthcare Sterile Processing Association (HSPA) (www.myhspa.org), and the Society of Gastroenterology Nurses and Associates (SGNA) (www.sgna.org).

6.3.2 Frequency of education, training, and competency verification

Personnel involved in endoscope processing shall be provided education, training, and complete competency verification activities related to their duties upon initial hire; annually; at designated intervals; or whenever new endoscope models, new processing equipment, or products such as new chemicals are introduced for processing. Processing activities should be closely supervised until competency is verified and documented for each processing task, from point of use through storage of the endoscope and transport to the next point of use.

Rationale: Breaches in processing related to insufficient model-specific training and competence have resulted in patient exposures (FDA MDR 8811666, 2019 [346]; McFeeters, 2016 [210]; Bauman, 2014 [83]; Washington State, 2014 [373]; Minnesota Department of Health, 2010 [212]; Haluska and Kiszie v. Forbes, 2005 [170]).

6.3.3 Responsibilities of personnel providing training

Facility personnel providing orientation, education, training, or competency verification for personnel processing flexible endoscopes should:

a) maintain the competence necessary to provide education, including the effective use of technologies to optimize practice and adherence to hand hygiene practices;

b) use regulatory and evidence-based professional guidelines as the foundation for education and training activities; and

c) periodically, at least annually, re-educate and reassess the competency of processing personnel and document completion of education, training, and competency verification activities.

6.3.4 Education and training

6.3.4.1 Personnel handling flexible endoscopes at the point of use

Education and training of personnel handling flexible endoscopes at the point of use should include:

a) proper endoscope handling;

b) point of use treatment after the procedure for precleaning the endoscope;

c) information to include in transport handoff, such as the completed procedure time and patient identifier, date and time of use, location, and time point of use treatment was completed (see 7.2.2);

d) removal of single-use items; and

e) transport of the endoscope and reusable accessories to the decontamination area as described in 7.3.2.

Rationale: Inadequate point of use treatment has contributed to processing failures (Ofstead, 2017 [246]; Ofstead, 2018a [237]) and patient exposure and infection (Kumarage, 2019 [203]; Ottawa Public Health, 2019 [250]).

6.3.4.2 Endoscope processing personnel

Education and training for endoscope processing personnel should include:

a) proper endoscope handling;

b) procedures for leak testing, cleaning, inspecting, disinfecting, sterilizing, packaging, and storing each specific endoscope make and model, including equipment and equipment connections;

NOTE Educational, training, competency verification, and other materials and information are available from endoscope manufacturers, AER manufacturers, sterilizer manufacturers, chemical solution and HLD manufacturers, professional associations, and professional journals.

c) identification of items that are single use and intended to be discarded after use;

d) all aspects of decontamination (e.g., disassembly, manual and mechanical cleaning methods and how to monitor their effectiveness, microbicidal processes, equipment operation, inspection, standard precautions, and engineering and work practice controls);

e) the operation of the specific manual and mechanical cleaning processes and equipment, manual and mechanical HLD processes, and sterilizing systems used by the health care facility, and the methods and equipment used to verify operation;

f) facility and processing area policies and procedures regarding high-level disinfection and sterilization, infection prevention and control, attire, hand hygiene, and compliance with local, state, and/or federal regulations;

g) workplace safety related to chemical use and biological hazards (see also 6.4);

- OSHA standards and requirements;
- Applicable personnel exposure monitoring specific to chemicals used;
- Recognizing and responding to exposure-related symptoms (e.g., difficulty breathing, skin irritation, eye tearing, mucous membrane irritation);
- Location and correct use of PPE;

— Location and use of SDS;

— Location and use of chemical spill kit(s); and

— Workplace-specific policies and procedures related to endoscope processing, high-level disinfection, and sterilization;

h) the process of leak testing when indicated in the manufacturer's written IFU;

i) the process of obtaining and documenting quality control monitoring results;

j) the process for visual inspection of endoscopes using lighted magnification and the use, care, and handling of a borescope;

k) the process for cleaning verification procedures, including method(s) for conducting the testing and interpreting the results; and

l) the process for removing a damaged endoscope from service and sending it for repair.

6.3.5 Competency verification

Competency verification activities should include monitoring processing personnel for their:

a) compliance with facility policies and procedures and manufacturers' written IFU, and adherence to regulatory requirements, for each type of endoscope processed at the facility; and

b) level of proficiency in processing procedures.

6.3.6 Documentation

Education, training, and competency verification activities should be provided and documented for all processing personnel on procedures for the processing of all endoscopes and the use of all AERs and sterilizers used at the facility.

Rationale: Initial and ongoing education, training, and competency verification can decrease the possibility of operator error during processing procedures and help to ensure that personnel are knowledgeable regarding the most current data and techniques for processing. Education, training, and competency verification are important aspects of any program intended to protect patients and employees from potential safety hazards and to help the employee recognize unsafe conditions or work practices and when, how, or why to employ protective measures. Health care facility policies and procedures are a necessary part of any education, training, and competency verification program. Providing education and training introduces new information and facilitates the development of knowledge and skills related to endoscope processing. Competency verification activities measure individual performance and provide a mechanism for documentation. Documentation of education, training, and competency verification is required by regulatory and accreditation agencies.

6.4 Standard precautions

Standard precautions represent a philosophy that assumes that all patients and all body fluids and items that have contacted body fluids are potentially infectious. Standard precautions include hand hygiene and wearing PPE to avoid contact with contaminated items, blood, or body fluids. Because it is not possible to specify a protective barrier for every situation that can occur, a risk assessment on the potential for exposure is necessary. The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) [231] includes the following requirements:

a) Precautions should be taken to prevent injuries from sharp objects (e.g., needles, scalpels, broken glass).

b) Sharp objects must be placed in puncture-resistant, leak-proof on the sides and bottom, closeable containers, and labeled with an OSHA-compliant label.

c) PPE should be used to prevent exposure to blood or body fluids.

d) Hands and other skin surfaces that are contaminated with potentially infectious fluids should be immediately and thoroughly washed.

e) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure to chemical or biological materials.

f) Food and drink should not be kept in refrigerators, freezers, or cabinets or on shelves, countertops, or benchtops where blood or other potentially infectious materials are present.

g) Employees should receive education, training, and complete competency verification activities on bloodborne pathogens.

See also CDC (2002) [105] and CDC (2007) [106].

Rationale: If all items are treated as infectious, then the risk of personnel exposure is reduced, especially when handling items from patients whose infectious status is unknown.

6.5 Hand hygiene

Policies and procedures on hand hygiene should be developed and communicated to employees. Such policies should be approved by infection prevention and control personnel or the designated employee health personnel. Considerations include, but are not limited to, the following:

a) Fingernails should be kept short and clean and should not extend beyond the fingertips.

b) Artificial nails, including gels, extensions or tips, acrylic overlays, or other enhancements, should not be worn.

c) Each facility should develop its own policy regarding the use of nail polish, including clear nail polish, as the issue remains unresolved and requires further study.

d) Hands should be cleaned according to CDC or WHO guidelines (CDC, 2002 [105]; WHO, 2009 [377]).

e) Hand hygiene with soap and water should be performed whenever the hands are visibly soiled.

f) Alcohol-based hand sanitizers are the preferred method for hand hygiene when hands are not visibly soiled.

g) Hand hygiene should be performed before and after glove use.

Rationale: Careful attention to hand hygiene can minimize the potential for acquiring or transmitting disease. Artificial nails can promote the growth of fungus under the nails (AORN, 2018c [37]; Baumgardner et al., 1993 [83]; Jeanes and Green, 2001 [183]; Porteous, 2002 [256]; Salman, et al., 2002 [285]; CDC, 2002 [105]).

6.6 Attire

6.6.1 General considerations

General considerations for attire to be worn in the processing area include the following:

a) All personnel entering the processing area should change into clean uniforms that are provided by and donned at the facility.

b) Attire should be changed daily or more often as needed (i.e., when wet, grossly soiled, or visibly contaminated with blood or other bodily fluids).

c) Reusable uniforms should be laundered by a health care-accredited laundry (ANSI/AAMI ST65 [15]; AORN, 2018d [38]).

d) All head and facial hair (except for eyebrows and eyelashes) should be completely covered (AORN, 2018d [38]).

e) Jewelry and wristwatches should not be worn in the processing area (AORN, 2018d [38]).

f) Shoes worn in the processing area must be clean, have non-skid soles, and be sturdy enough to prevent injury if an item drops on the foot. Liquid-resistant shoe covers should be worn if there is potential for shoes becoming contaminated and/or soaked with blood or other bodily fluids (29 CFR 1910.1030) [231].

g) The use of cover apparel when employees leave the area to travel to other areas of the health care facility should be determined by each facility and should comply with state and local regulations (AORN, 2018d [39]). Reusable cover apparel should be laundered daily and changed when soiled.

h) Remove uniform before leaving the health care facility unless the facilities are connected by an internal walkway (AORN, 2019a [35]).

Rationale: Clean attire minimizes the introduction of microorganisms and lint from personnel to items being processed and to the environment. Liquids can act as vehicles for the transfer of microorganisms from soiled materials and from the skin of personnel; therefore, wet surgical attire should be considered contaminated. Controlled laundering of garments reduces the risk of transferring pathogenic microorganisms from the health care facility to the home. Jewelry should not be worn because it is not easily or routinely cleaned, it can harbor microorganisms, it can become dislodged and damage items, and it can cause holes in gloves or other barrier protection. Wristwatches and rings, in particular, can catch on equipment or instruments, injuring personnel or damaging the item or packaging. Removing wristwatches and jewelry allows for more effective hand hygiene (CDC, 2002 [105]; Graves, 2006 [166]; Trick, 2003 [313]; Field, 1996 [148]).

6.6.2 Personal protective equipment

The OSHA bloodborne pathogen regulation (29 CFR 1910.1030) [231] and the OSHA Hazard Communication Standard (29 CFR 1910.1200) require that each facility have in place an exposure control plan that outlines the potential hazards that personnel might encounter while on the job. The plan should also identify the engineering controls, work-practice controls, and preventive and post-exposure medical care procedures that will be used to maintain the safety and health of employees. In the processing area, these measures will include the use of PPE. PPE should be selected and worn based on an assessment of the potential risk of exposure during the task to be performed and compliant with OSHA's Personal Protective Equipment Standards (29 CFR 1910.132 to 1910.138).

a) In addition to the attire recommended in 6.6.1, personnel working in the decontamination area should wear general-purpose utility gloves and a liquid-resistant covering with long sleeves to the wrist (for example, a protective gown).

b) Processing personnel should use a style of glove that prevents contact with contaminated water. For this purpose, exam gloves should not be used for decontamination. General- purpose utility gloves fitted at the wrist or above should be used.

c) When performing decontamination duties, the highest level gown should be worn (ANSI/AAMI PB70 [9].

Table 2—Barrier Gown liquid barrier performance class

ANSI/AAMI PB70 barrier performance	Test	Result	Anticipated risk of exposure: Fluid amount, spray or splash, pressure on gown or drape
Level 1	AATCC 42:200	≤ 4.5 g	Minimum
Level 2	AATCC 42:2000 AATCC 127:1998	≤ 1.0 g ≥ 20 cm	Low
Level 3	AATCC 42:2000 AATCC 127:1998	≤ 1.0 g ≥ 50 cm	Moderate
Level 4	ASTM F1671:2003 (surgical gowns and other protective apparel) ASTM F1670:2003 (surgical drapes and drape accessories)	Pass Pass	High

NOTE 1 The barrier performance class may be stated on the label as the barrier level or test method. Reprinted from AORN Guidelines.

NOTE 2 AATCC=American Association of Textile Chemists and Colorists and ASTM=American Society for Testing and Materials.

NOTE 3 Using TIR11:2005/(R)2015, *Selection and use of protective apparel and surgical drapes in health care facilities* [19], you can make your own table that reflects the AORN table. The first and last columns are taken from Table 3 and the second and third are from Table 2.

d) PPE should also include a fluid-resistant face mask, liquid-resistant shoe covers (if there is potential for shoes to become contaminated and/or soaked with blood or other bodily fluids), and eye protection. PPE used to protect the eyes from splash could include goggles, full-length face shields, or other devices that prevent exposure to splash from all angles. If noise levels exceed OSHA permissible levels for the OSHA-designated time duration, hearing protection should be available (29 CFR 1910.95 g).

e) Reusable gloves, glove liners, aprons, and eye-protection devices should be decontaminated, according to the manufacturer's written IFU, at least daily and between employees. If their integrity is compromised, items should be discarded. Torn gloves should be removed, and hands should be thoroughly washed before donning new gloves.

f) When PPE worn during processing is removed, hand hygiene should be performed immediately.

g) PPE should be changed between performing decontamination and handling disinfected endoscopes.

h) Before leaving the cleaning area, employees should remove all protective attire, being careful not to contaminate the clothing beneath or their skin and perform hand hygiene. Designated areas, with the necessary containers, should be provided for donning and removing protective attire.

Rationale: Contaminated endoscopes and other medical devices are sources of microorganisms to which personnel could be exposed through nicks, cuts, or abrasions in skin or through contact with the mucous membranes of the eyes, nose, or mouth. PPE will minimize the potential for employee exposure to bloodborne and other disease- producing organisms and chemicals used in the processing of endoscopes. Wearing heavy-duty, waterproof gloves while handling contaminated items decreases the potential for puncture, limits the microbial burden on hands, and decreases the risk of cross-contamination. Gloves do not offer absolute protection, however, because they can develop small leaks as a result of the stresses of the cleaning process (DeGrott-Kosolcharoen and Jones, 1989 [130]). Gloves that are too short, do not fit tightly at the wrist, or lack cuffs might allow water to enter when the arms move up and down. Hand hygiene performed after removal of PPE can prevent further contamination of the worker or environment. When the integrity of reusable gloves, aprons, or protective eyewear is compromised, they cease to function as a protective barrier. See also FDA (2008) [342].

Fluid-resistant face masks are an OSHA requirement and help to protect personnel who are cleaning contaminated items from splash or splatter that could contain pathogens (29 CFR 1910.1030) [231]. Eye protection reduces the risk of eye contact or injury from blood, body fluids, or other potentially infectious materials or hazardous chemical agents. Liquid splashes and aerosols can contact the eyes from any direction, including settling out of the air from above.

7 Decontamination processes

7.1 General considerations

Cleaning is the most critical step in effective processing of flexible and semi-rigid endoscopes, beginning with point of use treatment, followed by meticulous manual cleaning in the endoscope processing area; all of which precedes the disinfection or sterilization process. Cleaning is intended to remove the clinical soil so that the subsequent disinfection or sterilization process is effective. Thorough attention to cleaning is crucial for overall processing effectiveness and patient safety. Failure to perform effective cleaning can result in disinfection failure (Kumarage, 2019 [203]; Ofstead, 2018a [237]; Ofstead, 2018b [242]; Ofstead, 2017 [246]; Ofstead, 2016 [247]; Ofstead, 2015 [235]) or sterilization failure (Ofstead, 2017 [246]) and outbreaks of infection can occur (Kumarage, 2019 [203]; Galdys, 2019 [158]; FDA MDR 8379810, 2019 [322]). Cleaning consists of manual and mechanical processes that include wiping, brushing, and

flushing all external surfaces and internal channels using detergent solutions and cleaning accessories. Thorough rinsing of all detergents is important to remove detergent residuals.

The cleaning process begins at the point of use. When allowed to dry, soils become more difficult to remove. Soils are also known for their corrosive effects on material. Risk of biofilm formation is also increased by surface damage. To help prevent formation of biofilm or endoscope damage, cleaning should occur as soon as possible after the endoscope is used. Biofilm consists of accumulated biomass of bacteria and extracellular materials that tightly adhere to a surface and are difficult to remove. Biofilm effectively protects microorganisms from ordinary cleaning methods. It can form on many surfaces but is particularly problematic on devices with lumens, such as endoscopes. Prompt cleaning reduces or eliminates the population of biofilm-forming microorganisms and thus can help prevent the formation of biofilm (ANSI/AAMI ST79 [17]). Failure to promptly and properly initiate cleaning of endoscopes after use can increase the difficulty of cleaning and decrease the effectiveness of disinfection and/or sterilization.

Effective processing, including cleaning, is a challenging task and prone to human error (Joint Commission, 2018 [187]; Ofstead, 2010 [245]; Ofstead, 2018a [237]; Ofstead, 2018b [242]; Ofstead, 2017 [246]; Armellino, 2018 [70]; Ofstead, 2019 [240]; California Health and Human Services Agency, 2017 [100]; CMS, 2015a [120]; CMS, 2015b [121]; CMS, 2015c [122].

7.1.1 The appropriate cleaning methods for flexible endoscopes are based on:

a) the device manufacturer's written IFU;

b) the type of cleaning solutions, accessories and equipment used to clean the device;

c) the cleaning solution manufacturer's written IFU; and

d) any processing equipment manufacturer's written IFU.

7.1.2 Endoscope, cleaning equipment, and cleaning solution IFU should be followed during the cleaning process for endoscopes. In the event of conflict, the endoscope manufacturer should be contacted for clarification. Cleaning steps include the following:

a) point of use treatment;

b) transporting the endoscope from the point of use to the processing area as soon as possible;

c) leak testing;

d) manual and/or FDA-cleared automated cleaning (see 7.6 and 7.7);

e) thorough rinsing;

f) exterior drying and channel purge; and

g) inspection and testing for cleanliness.

Nonimmersible endoscopes should not be used, as they cannot be adequately processed.

7.2 Point of use treatment

7.2.1 General considerations

To prevent buildup of bioburden, development of biofilms, and drying of secretions, point of use treatment is performed immediately after completion of use of the device. It is imperative that the written IFU from the endoscope, cleaning equipment, and cleaning solution manufacturers are followed. When labelled for this purpose, commercially available sponges or wipes can be used for point of use treatment.

7.2.2 Procedure

The steps listed below are typical of the overall process for point of use treatment of a flexible or semi-rigid endoscope. Actual instructions for cleaning an individual endoscope will vary based on manufacturers' written IFU. Before the endoscope is detached from the light source and/or video processor:

a) Don PPE. Personnel performing point of use treatment and handling contaminated flexible endoscopes should wear PPE that includes

   1) fluid-resistant surgical masks in combination with eye protection devices, such as goggles, glasses with solid side shields, or chin-length face shields;

   2) fluid-resistant gowns (see ANSI/AAMI PB70 [9]);

   3) general purpose utility gloves fitted at the wrist or above; and

   4) liquid-resistant shoe covers (if there is potential for shoes becoming contaminated and/or soaked with blood or other bodily fluids, see 6.6.1 and ANSI/AAMI ST79 [17]).

b) Prepare a cleaning solution. The endoscope manufacturer's written IFU should be referenced for types of compatible cleaning agents, and the solution manufacturer's written IFU should be referenced for preparation of the chosen cleaning solution.

c) Wipe the insertion tube according to the manufacturer's written IFU with a clean, non-linting cloth or wipe or a non-abrasive sponge soaked in water or freshly prepared cleaning solution as soon as possible after the endoscope is removed from the patient or the procedure is completed. Ensure that all endoscope controls are in the free and unlocked position. The cloth or sponge should be single-use and disposed of after use.

d) Place the distal end of the endoscope in the cleaning solution and suction the solution through the instrument/suction channel as indicated in the endoscope manufacturer's written IFU.

e) During point of use treatment of an endoscope with an elevator mechanism, while continuing the immersion and the aspiration, raise and lower the forceps elevator three times by turning the elevator control level or as per the manufacturer's written IFU for the endoscope.

f) Flush the air/water channels with solution using the endoscope's cleaning adapter or by IFU-instructed air/water flow.

g) Flush any other channels (e.g., auxiliary water or elevator channels) with solution.

h) Flush each lumen as directed in the manufacturer's written IFU and until clear.

i) Detach the endoscope from the light source and suction pump.

j) Remove disposable accessories, if used.

k) Attach a fluid-resistant cap over any electrical components, if applicable.

l) Visually inspect the endoscope. If there is any evidence of damage, refer to the manufacturer's written IFU for further processing instructions. Tag the endoscope for further review. Refer to Section 14.

m) Sinks should be cleaned, disinfected, and rinsed between uses with a disinfectant approved by a multidisciplinary team (see Section 5) and in accordance with the IFUs for the disinfectant and the sink.

Hand-off communication from point of use to the decontamination area shall include at minimum, patient identifier, date of procedure, and time of point of use treatment was completed. Other information that may be helpful is the completed procedure time, location of the procedure, and employee contact.

When there is a delay and/or failure to perform point of use treatment, the endoscope should be processed using delayed processing protocols described in the device manufacturer's IFU.

Rationale: Flushing helps to remove excess soil and ensures that the channels are not blocked, debris is removed, and channels are moistened for further processing.

7.3 Transport of contaminated endoscopes

7.3.1 General considerations

Improper containment and transport of contaminated endoscopes represents a potential risk of infection transmission to staff and patients. Precleaned endoscopes are still considered contaminated and appropriate precautions and procedures should be followed. Endoscopes should be transported immediately after point of use treatment to the decontamination area.

The manufacturer's written IFU should be reviewed to determine any necessary point of use treatment, disassembly, or safety precautions in preparation for transport of the endoscope, accessories (e.g., biopsy forceps) and components (e.g., valves) from the patient procedure area to the processing area.

7.3.2 Procedure

Each endoscope should be isolated and transported with its components in a closed container or closed transport cart to the next stage of processing, as it is considered contaminated. The transport cart or container must be labeled with a visible fluorescent orange, orange-red, or red label containing a biohazard legend and must meet OSHA requirements (29 CFR 1910.1030) [231] for transporting hazardous items. The closed container or closed transport cart must be nonporous, leak-proof on its sides and bottom, puncture-resistant, and large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes. When endoscopes are transported on cart tops, a bag with an affixed biohazard label and designed for containment and transportation of soiled endoscopes may be used.

Soils on endoscopes and accessories should be kept moist, e.g., by applying a pretreatment solution, placing a towel moistened with water (not saline) over the items or placing items inside a package designed to maintain humid conditions, but not submerged in a solution. Keeping the endoscopes and accessories moist is not intended to extend time before processing.

Flexible endoscopes should be transported in a horizontal position, not suspended. When no other option is available and a dumbwaiter elevator or lift is used to transport both clean/sterile and contaminated supplies, they should be separated, and the transport carts should be covered or enclosed. All items, clean or soiled, should be contained in transport containers, and must be labeled biohazard.

Steps in the transport of endoscopes are as follows:

1) Separate endoscopy accessories from the contaminated endoscope to prevent puncture and penetration damage.

2) Place endoscopes and accessories in a container to prevent damage, including by naturally coiling each in large loops.

3) Hand-off communication from the transporter to the processing location should include:

    a) confirmation that the endoscope was transported correctly, and all accessory parts are present;

    b) the date and time of completion of use of that device;

    c) the time of point of use treatment; and

    d) patient identifier.

Rationale: Keeping the endoscope and accessories moist helps dilute, soften, and ease removal of organic soils (AORN, 2018e [39]). Allowing organic material to dry on the surface and in the channels of the endoscope makes the cleaning process more difficult. Fluid might leak from the contaminated endoscope if transported vertically. When suspended, the endoscope might become damaged because of compression on dependent components. Including completion of use time and point of use treatment time in the hand-off communication determines workflow for processing personnel.

7.4 Leak testing

7.4.1 General considerations

Leak testing, when applicable, should be performed as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions. Follow the endoscope manufacturer's written IFU for acceptance criteria of the leak testing protocol, including quality controls. Flexible endoscopes that cannot be leak tested should not be used. Automated leak testers should be placed on a calibration schedule to verify the leak tester is producing the correct pressure. Manual handheld leak testers and leak tester tubing should be inspected for damage, leakage, and pressure output (kPa). Pressure verification should be performed for each type of leak tester in the facility each day that endoscopes are used; calibration ensures that an endoscope will be challenged with the proper pressure each time when being tested for leaks. Documentation of testing results should be recorded. The manufacturer's written IFU for testing each type of leak tester (manual or mechanical) used in the facility should be followed to ensure they are properly functioning.

Rationale: Leak testing can detect damage to the endoscope that could, if undetected, allow for fluid invasion into the areas not designed for fluids and pose a potential risk of cross-contamination. These fluids can be a combination of accumulated water, chemicals, and/or biological matter that have collected from the time the endoscope's integrity was breached until the time the hole is identified. Over-coiling can mask a hole and allow it to go undetected.

7.4.2 Leak testing procedures

Multiple types of leak testing processes are available.

a) Wet leak tests require immersion of the pressurized endoscope in clean water and inspection for bubbles emanating from the device, which signal a leak from the endoscope.

b) Dry leak tests also pressurize the endoscope and detect a decrease in pressurization, which can signal a leak.

c) Manual testing requires the user to select and maintain the selected pressure, whereas mechanical leak tests automatically achieve the selected pressure.

The manufacturer's written IFU for the selected leak test should be followed. General considerations include the following:

a) Personnel performing the leak testing should wear PPE.

b) Prior to leak testing, the fluid-resistant cap should be applied, if indicated in the manufacturer's written IFU.

c) The largest surface counter or sink area available should be used to accommodate an open, minimally coiled endoscope for the test.

d) At a minimum, the manufacturer's recommended time for pressurization should be followed to achieve an accurate test.

e) Wet leak testing requires a clean sink with clean water without detergent.

f) Leak testers shall be cleaned and decontaminated according to the facility's policy and the manufacturer's written IFU.

7.4.3 Manual (dry) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

a) Remove all detachable parts from the endoscope (e.g., single-use valves and biopsy port covers).

b) Ensure that the fluid-resistant cap is attached, if applicable.

c) Attach the leak tester securely at the connector.

d) Pressurize the endoscope to the indicated pressure on the leak tester gauge.

e) Place the endoscope in a loose configuration.

f) Gently rotate each directional knob and elevator control while watching for changes in the established pressure.

g) Manipulate video or remote switches in a circular manner to detect holes more readily in these components.

h) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.

i) Maintain pressure and inspection for a minimum of 30-seconds.

j) Release air pressure from the endoscope before removal of the leak testing unit. In the event of a failure, see 7.4.8.

k) If the endoscope passes the dry leak test, proceed to the next step of processing.

l) Document the outcome of the leak test.

m) Detach the leak test connector from the endoscope.

7.4.4 Manual (wet) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

a) Remove all detachable parts from the endoscope (e.g., single-use valves and biopsy port covers).

b) Ensure that the fluid-resistant cap is attached, if applicable.

c) Attach the leak tester securely at the connector.

d) Pressurize the endoscope to the indicated pressure on the leak tester gauge.

e) Place the endoscope in a loose configuration in a large sink with a sufficient volume of clean water to completely immerse it.

f) Using a new syringe, completely flush all channels with water to remove trapped air.

g) Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs. Also watch for changes in the established pressure.

h) Manipulate video or remote switches in a circular manner to detect holes more readily in these components.

i) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.

j) Perform a complete visual inspection of the endoscope for leaks. If static bubbles are attached to the endoscope, brush them away and inspect to ensure that the bubbles do not return.

k) Maintain pressure and inspection for a minimum of 60-seconds.

l) Remove the entire endoscope from the test water.

m) Depressurize according to the endoscope manufacturer's written IFU before removing the leak tester. Release air pressure from the endoscope before removal of the leak testing unit. In the event of a failure, see 7.4.8.

n) If the endoscope is water-tight, proceed with cleaning and disinfection processes.

o) Document the outcome of the leak test.

p) Detach the leak test connector from the endoscope.

7.4.5 Mechanical (dry) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

a) Prepare automated leakage tester and tubes.

b) As applicable, power on the printer.

c) Power on the automated leak tester.

d) Position the endoscope(s) for leak testing as prescribed by the manufacturer's written IFU.

e) Ensure that fluid-resistant caps are attached to the endoscope, as applicable.

f) Connect the leak tester tubes to the endoscope(s).

g) Scan or enter user and endoscope information.

h) Select the "start" and allow the automated leak tester cycle to complete the test.

i) If the endoscope receives a pass indication, proceed with the next step of processing.

j) If the endoscope received a fail result, check connections and repeat the test. If failure occurs again, proceed with a wet leak test in the manual leak testing mode, as prescribed by the manufacturer's written IFU, to determine the leakage area. Once the leakage area is determined, see 7.4.8 for recommendations on processing a leaking endoscope.

k) Document the outcome of the leak test.

l) Detach the leak test connector from the endoscope.

7.4.6 Mechanical (wet) leak testing

The endoscope and leak tester manufacturers' written IFU should be followed. Unless otherwise specified by the manufacturer's written IFU, the following steps are recommended:

a) Remove all valves and biopsy port covers.

b) Ensure that the fluid-resistant cap is attached prior to immersion, if applicable.

c) Attach the leak tester.

d) Turn the air compressor on and pressurize the endoscope.

e) Establish pressurization by confirming that the bending rubber has expanded.

f) Place the endoscope in a loose configuration in a large sink with a sufficient volume of clean water without detergent to completely immerse it.

g) Using a new syringe, completely flush all channels with water to remove trapped air until no bubbles emerge from the endoscope.

h) Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs.

i) Manipulate video or remote switches in a circular manner to challenge the integrity of these components while looking for bubbles.

j) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.

k) Perform a complete visual inspection of the endoscope for leaks. If static bubbles are attached to the endoscope, brush them away and inspect to ensure that bubbles do not return.

l) Maintain pressure and inspection for a minimum of 60-seconds.

m) Remove the entire endoscope from the test water.

n) Stop pressurization by turning off the air supply.

o) According to the manufacturer's written IFU, remove the leak tester from the air compressor and listen for the sound of evacuated air.

p) If the endoscope is water-tight, proceed with cleaning and disinfection processes. In the event of a failure, see 7.4.8.

q) Document the outcome of leak test.

r) Detach the leak test connector from the endoscope.

7.4.7 Mechanical leak testing using an AER

a) Follow the endoscope and AER manufacturers' written IFU.

b) Document the outcome of the leak test.

Conducting mechanical leak testing using an AER cannot substitute for the leak testing recommended in the endoscope manufacturer’s written IFU.

7.4.8 Leak test failures

a) If a leak has been identified, follow the modified processing steps according to the endoscope manufacturer's and/or repair company’s written IFU or official company documentation.

b) Re-evaluate the leak testing process if fluid invasion is a recurring problem.

c) If the endoscope fails leak testing, affix a label to the device to identify defective equipment for repair, remove the endoscope from service, and follow facility guidelines for repair.

d) Report the leak test failure per organizational policy and procedure, including the endoscope product identification and traceability information .

7.5 Cleaning

7.5.1 General considerations

Cleaning should begin as soon as possible after confirming that the endoscope does not have any leaks. The endoscope manufacturer's validated cleaning process should be followed. If there is a delay in processing the endoscope that exceeds the manufacturer's recommended time, the endoscope should be cleaned according to the manufacturer's written IFU for delayed processing (AORN, 2018e [40]). The cleaning steps listed in 7.6 represent typical cleaning flow for endoscopes, their removable parts, and endoscopic accessories; however, individual manufacturers' validated instructions might vary. Personnel performing manual cleaning, rinsing, and drying must wear PPE (29 CFR 1910.1030) [231].

Ensure that cleaning is initiated in the timeframe prescribed in the manufacturer's written IFU. If no timeframe is given, manual cleaning should be initiated within one hour or as determined by the facility based on their own documented risk assessment.

NOTE See ANSI/AAMI ST90:2017, 8.2.3 for guidance on risk assessment and corrective action [18].

7.5.2 Detachable parts

Detachable parts and valves pose unique concerns. To minimize risk of transmission of infection, any one of the following measures are recommended:

1) Use of single-use biopsy port caps and single-use valves.

2) Sterilization of reusable valves and caps, preferably using steam sterilization when materials are compatible.

3) High level disinfection of valves and caps, either keeping the valve/caps together with the endoscope as a set or tracking the individual valve/cap to the patient and the procedure.

7.6 Manual cleaning steps

The following steps are recommended:

a) Use only compatible detergents recommended by the endoscope manufacturer or validated by the solution manufacturer for compatibility and efficacy (see Annex D).

b) Prepare fresh cleaning solution in a clean sink or basin for each endoscope according to the detergent manufacturer's written IFU for temperature, concentration, and water quality. Monitor the temperature of the cleaning solution (if specified).

c) Place the endoscope in the cleaning solution, keeping it completely immersed in the cleaning solution, according to the endoscope and cleaning solution manufacturers' written IFUs.

d) Clean the endoscope's exterior surfaces with a fresh non-linting cloth or sponge. The cloth or sponge should not be reused from the point of use treatment. If brushes are used, follow the endoscope manufacturer's written IFU for the type of brush to be used.

e) Clean all valve cylinders, openings, and forceps elevator housings with a cleaning brush of the length, width, and material designated in the endoscope manufacturer's written IFU (AORN, 2018e [40]).

    1) Clean the elevator mechanism and the recesses surrounding it with a cleaning brush of the length, width, and material specified in the endoscope manufacturer's written IFU (AORN, 2018e [40])).

    2) Raise and lower the elevator per the manufacturer's written IFU when flushing and brushing the elevator recess.

    3) Raise and lower the elevator throughout the cleaning process (AORN, 2018e [40])).

f) Brush accessible channels (e.g., the instrument/suction channel) according to the endoscope manufacturer's written IFU until there is no visible debris and for the length of time specified. Use brushes of the length, width and material specified by the endoscope manufacturer's written IFU. Follow the brushing technique specified in the endoscope manufacturer's written IFU to clean the endoscope, keeping the endoscope immersed at all times.

g) Use cleaning brushes that are either:

- single-use and disposed of after cleaning (preferred), or
- reusable and cleaned, high-level disinfected or sterilized after each use, according to the manufacturer's written IFU.

h) Use the endoscope manufacturer's brush or equivalent cleaning device (see ASTM 3275-19 [44] and ASTM F3276-19 [45]).

i) Aspirate (suction) cleaning solution through the instrument/suction channel as recommended by the endoscope manufacturer's written IFU, using the required adapters.

j) Flush all channels according to the endoscope manufacturer's written IFU. If an automatic flushing system is used:

- the manufacturer's written IFU should be followed;
- a model-specific cleaning adapter, compatible and validated for use with the endoscope being processed by the flushing system manufacturer should be used;
- all connections should be correctly secured;
- a fresh cleaning solution should be used;
- verify that solution flows through each lumen;
- the endoscope channels should be flushed and exposed according to the endoscope, equipment, and cleaning solution manufacturers' written IFU;
- the endoscope channels should be flushed with water of the specified type in the volume or for the length of time specified in the manufacturer's written IFU;
- the connection tubing and equipment should be cleaned and disinfected according to the manufacturer's written IFU; and
- any quality assurance testing recommended by the manufacturer (e.g., daily volume verification) should be performed and documented.

NOTE Use of suction during manual cleaning might still be a necessary step, even when using an automated flushing pump. Follow the endoscope and pump manufacturers' written IFU.

k) Soak the endoscope in the detergent solution for the time specified in the detergent manufacturer's written IFU.

l) Rinse the exterior and interior surfaces of the endoscope with copious amounts of utility water (see AAMI TIR34 [23]) until all cleaning solution and debris is visibly removed. Some cleaning solutions might require multiple rinses in fresh water. Follow the endoscope, equipment, and/or cleaning solution manufacturers' written IFU for the recommended amount of water, number of rinses, and pressure (i.e., psi) to flush each endoscope channel.

m) Inspect the endoscope (see 7.8). Repeat the cleaning, brushing, and rinsing steps until there is no visible residual debris or solution remaining on the endoscope. Endoscopes that have been exposed to synthetic lipids, radiographic medium, simethicone (Ofstead, 2016 [239]; Barakat, 2019 [79]; Ofstead, 2019 [240]; Van Stiphout, 2016 [365]; Olympus, 2018 [248]; Fujifilm, 2013 [154]; Pentax, 2014 [252]), or certain patient medications (e.g., fish oil, some diabetes medications) or that were used in procedures with poor patient preparation, emergency procedures, or bloody procedures might require additional cleaning.

n) Dry the exterior surfaces of the endoscope with a clean, non-linting cloth.

o) Purge all endoscope channels with instrument air or filtered air from a flushing pump at the pressure and for the time indicated in the manufacturer's written IFU.

p) Clean, brush, and rinse all reusable and removable parts (e.g., valves, buttons, port covers, tubing) according to the manufacturers' written IFU.

   — Discard removable parts designed for single use (see 7.5.2).

   — Manually actuate the endoscope valves during cleaning.

q) Clean reusable endoscopy accessories (e.g., forceps, wires, baskets) according to their manufacturers' written IFU.

r) At a minimum, remove gloves and perform hand hygiene prior to inspection.

s) Sinks should be cleaned, disinfected, and rinsed between uses with a disinfectant approved by a multidisciplinary team (see Section 5) and in accordance with the IFUs for the disinfectant and the sink.

Rationale: Starting the cleaning process as soon as possible after leak testing helps prevent soil from drying on the device and might prevent biofilm from forming. Soil that remains on the endoscope can interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms. Manually actuating the endoscope valves during cleaning helps ensure cleaning of all internal parts. Rinsing with copious amounts of utility water helps ensure that all cleaning solutions and debris are removed. Purging endoscope channels with instrument air helps evacuate residual rinse water. Single-use brushes are preferred to reduce the risk of using brushes that haven't been cleaned and decontaminated between uses.

7.7 Automated cleaning, rinsing, and drying

Some AERs have cleaning cycles that are validated and FDA-cleared to replace manual cleaning of some endoscopes prior to placing them into the AER. An automated cleaning cycle on an AER is not intended to replace point of use treatment, and most AER automated cleaning cycles also are not intended to replace manual cleaning of endoscopes prior to placing them into the AER. If considering replacement of manual cleaning with a validated and FDA-cleared automated cleaning cycle, facilities should convene a multi-disciplinary team to conduct a risk assessment (see 13.14.2). Consult your AER manufacturer for validated data concerning cleaning capability and allowed FDA 510(k) claims. Verify that they meet or exceed current cleaning requirements set forth by the FDA. For duodenoscopes, the FDA currently recommends that "the AER cleaning cycle only be used as a supplement to thorough manual cleaning according to the duodenoscope manufacturer's instructions" (FDA, 2018 [344]).

NOTE Manual cleaning can be used in conjunction with automated cleaning.

7.8 Inspection and cleaning verification

7.8.1 General considerations

Cleaning verification and inspection includes visual inspection and cleaning verification testing and can include borescopic examination.

Using cleaning verification indicators after manual cleaning helps verify that the desired soil removal goal was achieved, and that the device can safely proceed to the selected disinfection or sterilization process (see Section 8). Visual inspection with lighted magnification and evaluation provides an opportunity to identify and remove from service

defective items that might put patients at risk for infection or injury or that might further damage the device until these items are repaired (AORN, 2018e [39]]; Barakat, 2018 [79]; Thaker, 2018 [309]; Ofstead, 2017a [244]; Ofstead 2017b [246]; Ofstead, 2018a [237]; Ofstead, 2018b [242]). Recent outbreak investigations reinforced that visual inspection of endoscopes can identify defects or residual contamination (Galdys, 2019 [158]; Kumarage, 2019 [203]; Rauwers, 2019 [262]; Ottawa Public Health, 2019 [250]). An endoscope that appears clean can harbor debris that cannot be seen without magnification (AORN, 2018e [39]). Borescopes enter the lumen and allow for improved visual inspection (AORN, 2018e [39]).

An endoscope that has repeatedly failed a cleaning verification test or is suspected of having damage should be sent to an appropriate repair service for evaluation (Ofstead, 2017 [246]; FDA MDR 8579952, 2019 [347]; FDA MDR 8495252, 2019 [348]; FDA MDR 8392535, 2019 [349]).

Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced (AORN, 2018e [39]). A label should be affixed to the device to identify defective equipment for repair.

Ensure PPE are not grossly soiled, and gloves are changed after cleaning steps before completing inspection and cleaning verification.

Rationale: Studies and FDA MAUDE reports have documented cases where endoscopes that were sent out for evaluation after failing cleaning verification tests had critical defects and damage that required repair or refurbishment.

7.8.2 Visual inspection

Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization (AORN, 2018e [39]).

Endoscopes, accessories, and equipment should be visually inspected and evaluated for:

a) cleanliness;

b) missing parts;

c) clarity and integrity of the lenses;

d) integrity of seals and gaskets;

e) moisture;

f) physical or chemical damage (e.g., cracks, peeling, buckling, stretching, holes);

g) function (e.g., broken bending section, kinks, angulation, ability to focus, if applicable) (AORN, 2018e [39]); and

h) changes in the endoscope's appearance.

Lighted magnification should be used to inspect endoscopes and accessories for external cleanliness and damage (AORN, 2018e [39]; FDA/CDC, 2018 [345]). Visual inspection should take place after manual cleaning in a well-lighted area with proper illuminance to enable detection of gross soil and other body substances (see 4.3.2, Table 1, and Annex C and Annex E). Where applicable, closely inspect the elevator and surrounding recess for visible soil. According to the FDA/CDC, it is recommended that areas of the endoscope at the distal end be inspected using at least 5x magnification, 10x magnification for duodenoscopes (see FDA/CDC culture method, 2018 [345]).

7.8.3 Borescopic inspection

The internal channels of a flexible endoscope that are accessible can be inspected by a borescope or other appropriate inspection method. Those conducting the inspection should be trained to identify damage and retained contaminants. Refer to the endoscope manufacturer's written IFU, maintenance bulletins, and other labeling for direction on what is

considered a defective or damaged medical device that cannot be used and must be sent to the service provider for further inspection and potential service activities. If borescopic inspection findings are unclear, contact the endoscope manufacturer and/or repair service provider for guidance and refer to Annex E.

A borescope can be used periodically to inspect the accessible channels of flexible endoscopes at a frequency determined by the facility. When performed, this inspection step occurs on a dried endoscope after manual cleaning and prior to disinfection or sterilization. A dried endoscope can provide better visualization. If a borescope is used after disinfection/sterilization as a quality monitoring tool, the endoscope shall be processed again before clinical use.

An endoscope that has repeatedly failed a cleaning verification test or is suspected of having damage should be sent to an appropriate repair service for evaluation (see 13.5.2).

The borescope should be processed in accordance with the manufacturer's written IFU.

7.8.4 Cleaning verification

Before performing cleaning verification and inspection, personnel should ensure that PPE is not grossly soiled and that gloves are changed after cleaning steps.

High-risk endoscopes (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes, and as determined by the facility) shall be evaluated with cleaning verification tests after each use (see 13.5.3). Refer to Annex F for selection of an adequate cleaning verification test. Manual cleaning of flexible endoscopes that are not determined to be high-risk shall be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed). See F.4. Other factors to be considered when determining frequency include endoscope type, technician competency, procedural characteristics (e.g., duration, complexity, and heavy soiling), or delayed reprocessing.

8 High-level disinfection, liquid chemical sterilization, and terminal sterilization systems for flexible endoscopes

8.1 General considerations

There are a variety of biocidal methods available for disinfecting and sterilizing flexible endoscopes (see Annex I). To determine the method for a specific device, refer to the medical device manufacturer's written IFU and the intended use of the device. Ensure that the method is cleared by the FDA for use in health care facilities (www.fda.gov).

All flexible endoscopes that are introduced directly into the bloodstream or that contact a normally sterile tissue or body space during use are critical devices and shall be sterilized.

8.2 High-level disinfectant systems and liquid chemical sterilant processing systems and procedures

8.2.1 General considerations

High-level disinfection and liquid chemical sterilization are processes that use biocidal chemical solutions described by FDA as liquid chemical sterilants (LCS). Information on LCS/HLD solutions cleared by the FDA is provided on the FDA website. The list, which is updated periodically, provides information on the products' clearance for liquid chemical sterilization and/or high level disinfection, the contact times and temperatures required for each process, and whether the LCS/HLD solution is limited to use in an AER. To find LCS/HLDs cleared by FDA, go to www.fda.gov.

High-level disinfection is the minimum level of processing for semi-critical endoscopes. High-level disinfection traditionally is defined as a process that kills all microorganisms, in or on an instrument, except for bacteria spores when present in large numbers (see 3.30). The FDA further defines a high-level disinfectant as a sterilant used for a shorter contact time than when used for liquid chemical sterilization to achieve a 6-log10 kill of an appropriate *Mycobacterium species*.

Many LCSs and HLDs cleared by the FDA are labelled for use in both liquid processes. All HLD solutions are LCSs, based on passing the AOAC Sporicidal Activity Test as a sterilant. However, some HLD solutions require an extended

time (e.g., 22-32 hours) to pass the AOAC Sporicidal Test as a sterilant and therefore are labelled only for HLD and are not indicated for device liquid chemical sterilization.

Liquid chemical sterilization can be used to process semi-critical and critical heat sensitive endoscopes. Liquid chemical sterilization is different than thermal and gas (or vapor) low temperature sterilization. Liquid chemical sterilization is able to achieve a 6-$\log_{10}$ kill of the appropriate bacterial spore shown most resistant to the process in a full cycle, and a SAL cannot be determined. The FDA recommends that liquid chemical sterilization be used for heat sensitive, critical medical devices only when terminal sterilization methods are not feasible or not available. The information in the literature suggests that treatment with liquid chemical sterilants may not necessarily ensure the same sterility assurance as terminal sterilization using thermal or gas/vapor low temperature sterilization methods (Rutala and Weber, 2008 [283]; Rutala and Weber, 2016 [281]). Devices are not wrapped during processing and may not be contained adequately after processing in a liquid chemical sterilant, and there is no assured way to maintain sterility after the devices are processed.

High-level disinfection and liquid chemical sterilization can be achieved with manual or automated processes. Manual high-level disinfection and liquid chemical sterilization is not recommended due to variability and inconsistency in the personnel responsible for the process (see 8.2.4). The automated processes utilize Automated Endoscope Reprocessors (AER) or endoscope washer-disinfectors which is equipment designed to deliver the LCS/HLD solution to all parts of the endoscope to achieve effective LCS/HLD of the endoscope and its components. Processing endoscopes in an AER includes immersion or spraying of the endoscope, filling, or circulating LCS/HLD solution through the device channels for a timed exposure period, and rinsing of the endoscope surfaces and internal channels with water to remove the LCS/HLD residues.

The microbial quality of the water used to rinse endoscopes is an important aspect of liquid chemical sterilant/high level disinfectant processing. It is important to recognize that the microbial quality of the water will vary based on the facility and may recontaminate the processed endoscope (Seidelman, 2019 [288]; Ofstead, 2016 [247]). The LCS/HLD manufacturer's instructions for high level disinfection or liquid chemical sterilization will provide information on the quantity and quality of rinse water as well as the number of rinses and time required for each rinse in manual processes to reduce chemical residues to a safe level. Users also should follow the endoscope manufacturers' IFU and their recommended microbial quality requirement of the water to be used for rinsing (also see AAMI TIR34 [23]).

Effective drying of endoscopes can reduce the risk of increasing (or accelerating) proliferation following LCS and HLD (e.g., recontamination of the endoscope by waterborne microorganisms during rinsing) (Kovaleva, 2017 [201]; Ofstead, 2016 [247]; Ofstead, 2018 [242]; Perumpail, 2019 [254]; Saliou, 2015 [284]). Certain waterborne microorganisms, such as *Pseudomonas aeruginosa*, can pose an infection risk to a portion of the endoscopy patient population, especially those undergoing a bronchoscopy procedure or endoscopic retrograde cholangiopancreatography (ERCP) procedure (Kovaleva, 2013 [202]). Further, the presence of such microorganisms in conjunction with retained moisture can lead to the development of biofilms and further patient risk. This is a particular risk when tap water is used to rinse the endoscope following the antimicrobial process. As part of the facility water management plan, periodic microbial assessment of the AER and processing equipment should be considered to identify water contaminants or contaminated equipment which may contribute to recontamination of the device after high-level disinfection (Ofstead, 2016 [247]). Periodic microbial assessment of the water used for final rinse should be considered to identify any contaminants which can contribute to recontamination of the device after high-level disinfection (Ofstead, 2018 [242]; Seidelman, 2019 [288]; Ofstead, 2016 [247]).

Rationale: In studies where endoscopes harbored bacteria, including waterborne pathogens, following high-level disinfection despite adherence to processing guidelines, water used to rinse disinfected endoscopes was implicated (Ofstead, 2018 [242]; Seidelman, 2019 [288]; Ofstead, 2016 [247]).

8.2.2 Spill kits

Spill kits should be on-hand to deal with the maximum possible spill. Information about how to deal with a spill is available on the SDS and spill kits for most high level disinfectants are commercially available.

8.2.3 Automated high-level disinfection and liquid chemical sterilization processes

8.2.3.1 Automated high-level disinfection/liquid chemical sterilization features

An automated process can be more efficient and consistent than a manual process, resulting in less user exposure and avoidance of prolonged endoscope exposure to the toxic liquid chemical sterilant (LCS/HLD). Depending on the make and model of the AER or LCSPS, features might include the following:

a) a printer for documentation or electronic data transfer of cycle parameters, the endoscope ID, and the operator ID;

b) adjustable cycle times;

c) connector-less systems that do not require tubing attachments;

d) automated cleaning, high-level disinfection and/or liquid chemical sterilization cycles which incorporate turbulent flow technology or ultrasonic cleaning capabilities;

e) detection of channel obstruction;

f) reservoirs with heating elements that will provide and maintain the temperature of the LCS/HLD solution at the indicated contact temperature for the process;

NOTE Some LCS/HLD solutions have specific temperature requirements for effectiveness.

g) pressurized flow to fill the endoscope channels, bathe the exterior, and circulate the LCS/HLD continuously during the exposure time;

h) an automated MEC or MRC reader;

i) supplementary leak testing (see 7.4.7);

j) automatic rinsing with a programmable number of rinses;

k) an automatic alcohol flush;

l) an automatic air purge;

m) the ability to process two or more endoscopes in the same or separate chambers;

n) self-disinfection cycles;

o) pass through capability for separation of clean and dirty areas; and

p) a barcode scanner to facilitate the input of identifying information for each processed device.

8.2.3.2 Automated high-level disinfection/liquid chemical sterilization procedure

To ensure effective performance of AERs and LCSPSs, the user should observe the following:

a) Remove the PPE used for cleaning the endoscope and perform hand hygiene. New, clean, non-latex procedure gloves should be worn when handing the clean endoscope and accessories unless otherwise indicated by the type of procedure or recommended by the manufacturer. PPE used for decontamination should not be worn when handling an endoscope or any accessories that have completed the disinfection process.

b) Follow the AER or LCSPS manufacturer's written IFU for all procedures. Compare the endoscope manufacturer's written IFU to the AER or LCSPS manufacturer's written IFU. If there are any discrepancies between the two, a decision should be made by a multidisciplinary team based on the information available.

c) Ensure that the specified time, temperature, and number and quality of rinses are within the capability of the AER.

d) Filter incoming water and change the filter as recommended by the AER or LCSPS manufacturer's written IFU. The internal water piping system that does not come in contact with the LCS/HLD solution should be disinfected on a regular basis as directed by the manufacturer.

e) Verify that the cleaning detergent and/or LCS/HLD are available for cycle and that they are in the appropriate location (e.g., reservoir or bottle attachment site).

f) Document required information as per 13.4.1.

g) Process accessories as specified by the manufacturer's written IFU.

h) Use the quality testing device for the AER, if available, to ensure that solutions are flowing. Testing of this function should be performed at least weekly, after major repairs or whenever there is concern about equipment function.

i) Place the endoscope in basin per AER manufacturer's recommendation. Connect the endoscope channels to the AER or LCSPS connectors, if applicable.

j) Test the solution MRC or MEC according to the manufacturer's written IFU.

k) Close the AER or LCSPS and select the cycle.

l) Repeat the cycle if the original cycle is interrupted, because the liquid chemical sterilization/high-level disinfection of the device cannot be ensured if the cycle has been interrupted.

m) If the endoscope manufacturer requires it as part of the validated reprocessing protocol, perform a final flush of the endoscope channels with alcohol. However, if alcohol use is a concern because of its fixative properties, a multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should review the effects of alcohol on the endoscopes and establish a policy on its use (Costa et al., 2017 [125]).

n) Endoscopes that have completed an HLD cycle in an AER should undergo additional drying internally with instrument air to remove moisture, dried externally (see 8.2.5), and then stored in accordance with Section 11 to avoid contamination.

o) LCSPSs may utilize a spore test strip. Follow the spore test strip and LCSPS manufacturers' written IFU and also see 13.6.1.

p) Liquid chemically sterilized endoscopes intended to be used in a critical application should be used immediately after processing. They may also be used immediately in semi-critical applications. If not meant for immediate use, follow instructions for storage of high-level disinfected endoscopes.

q) If an endoscope is left in the basin of an AER or LCSPS for an extended period of time (i.e., more than one hour), the endoscopes should be put back through the HLD/liquid chemical sterilization cycle before it is stored/used.

r) If endoscope is transported to patient care room but not used, it shall be processed again prior to next patient use.

8.2.4 Manual high-level disinfection and liquid chemical sterilization processes

8.2.4.1 Manual processing procedure

Manual processing is not recommended but if necessary due to facility or resource limitations, consult the endoscope manufacturer's written IFU to determine the compatibility of the device with the selected LCS/HLD solution (see 8.2.4). To ensure safety and efficacy, the user should observe the following:

a) Use only those LCS/HLD solutions recommended by the endoscope manufacturer or that have been validated for use for both efficacy and compatibility and cleared by the FDA.

b) Use a timing device to assure correct soak time (AORN, 2018e [39]).

c) Use a clean, dry container.

d) While wearing PPE recommended in the manufacturer's written IFU, prepare the LCS/HLD product according to the manufacturer's written IFU.

e) Devices should be thoroughly cleaned, rinsed and excess moisture should be removed before they are immersed in the solution to avoid adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

f) Before immersion, check the expiration date of the solution. Completely immerse the device in the LCS/HLD solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with the LCS/HLD, as recommended. A channel irrigation device or syringe might be needed to fill all lumens with the LCS/HLD.

g) Use a solution test strip or chemical monitoring device to test the concentration of the active ingredients before each use. Only those solution test strips or chemical monitoring devices that have been cleared by the FDA for that LCS/HLD should be used. Quality control checks of the solution test strips, or chemical monitoring devices should be performed according to the manufacturer's written IFU.

h) When the concentration of the active ingredients falls below the MRC or MEC, discontinue use of the solution.

i) Ensure that the solution is at the minimum required temperature, as specified in the solution manufacturer's IFU. Document the temperature. Do not use a solution that is above or below the required temperature range. Use a calibrated thermometer to ensure that the soaking temperature meets that specified on the HLD label (AORN, 2018e [39]).

j) Ensure that exposure to chemical solutions and vapors is kept to a minimum, and below OSHA and ACGIH® occupational exposure limits.

k) Keep solutions covered to prevent evaporation.

l) Solutions that evaporate or drain below the soak level may require additional solution to facilitate complete immersion of the device. Before adding solution, first consult the LCS/HLD manufacturer's IFU to ensure that adding solution is permitted. The solution cannot be used beyond the original soaking solution expiration date (use life). Before being used, the solution must be tested for MRC or MEC.

m) Do not use solutions beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. An LCS/HLD product might be labeled for multiple-day use or (if it is a concentrate) for one-time use.

n) Do not use LCS/HLD solutions beyond their shelf life.

o) Store unopened solutions in a cool, well ventilated area at the temperature recommended by the manufacturer.

p) Dispose of LCS/HLD solutions and their containers in accordance with state and local regulations (e.g., neutralization of the product prior to disposal in the sewer system).

q) Endoscopes that have completed manual high-level disinfection or liquid chemical sterilization and are intended for use in a semi-critical application are not packaged and are to be thoroughly rinsed, dried internally and externally (see 8.2.5), and stored in accordance with Section 11.

8.2.4.2 Manual rinsing

Follow the endoscope and LCS/HLD solution manufacturers' written IFU on the quantity and quality of rinse water as well as the number of rinses and the time required for each rinse to reduce chemical residues to a safe level. Each rinse should be performed using fresh water. To prevent recontamination of the endoscope, the container or sink used to perform the rinse should be clean and should not be the same container or sink that was used to clean or disinfect the endoscope. The microbial quality of the water used to rinse endoscopes is important (see 8.2.1 and AAMI TIR34 [23]). Users should follow the endoscope and LCS/HLD solution manufacturers' written IFU for the required microbial quality of the water to be used for rinsing (also see AAMI TIR34 [23]). The specific procedure for rinsing is as follows:

a) Don fresh PPE, including gloves, skin and eye protection, fluid-resistant masks, and fluid-resistant shoe covers.

b) Thoroughly rinse all surfaces and channels of the endoscope and its removed components according to the endoscope and LCS/HLD solution manufacturers' written IFU in order to remove all traces of the disinfectant.

c) Use critical water for the final rinse (see AAMI TIR34 [23]) unless sterile water is specified by the manufacturer's written IFU. Follow the device manufacturer's written IFU for the specified rinse water quality.

Rationale: Following manufacturer's rinsing instructions prevents potential patient exposure and skin and mucous membrane injury from chemical residues. Use of sterile or critical water for the final rinse reduces the risk of contamination by waterborne microorganisms.

8.2.5 Endoscope drying

8.2.5.1 General considerations

The endoscope and its components should be dried after completion of the cleaning and disinfection process. Flexible endoscopes with channels should be dried for a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air (Ofstead, 2018 [242]; Barakat, 2018 [79]; Perumpail, 2019 [254]; Alfa, 1991 [53]). If after 10-minutes of drying moisture is still observed, extend drying time until no moisture is visible. Refer to Annex K for information on drying verification. Consult the endoscope manufacturer's written IFU for the maximum psi.

Endoscopes should never be stored wet or before decontamination has been completed as such storage supports the growth of microorganisms and biofilms (AORN, 2019a [71]; Beilenhoff et al., 2018 [87]).

A forced-air nozzle or drying cabinet used to dry manually cleaned endoscopes could become contaminated with residual bioburden. This could be a concern if the forced-air nozzle or drying cabinets are also used for drying or storing high-level disinfected endoscopes. In order to avoid intermingling manually cleaned endoscopes that are being dried before sterilization with disinfected endoscopes being dried before storage, consider using separate forced-air systems and cabinets for high-level disinfected endoscopes and manually cleaned (pre-sterilization) endoscopes. Cabinets and nozzles used for manually cleaned endoscopes should be frequently cleaned and disinfected to reduce cross-contamination.

NOTE Consider performing a risk assessment if the same drying implements are used both after high level disinfection and after manual cleaning.

Rationale: See Annex K.

8.2.5.2 Manual drying

Unless otherwise directed by the endoscope manufacturer, drying of endoscope channels is accomplished by flowing instrument air or HEPA-filtered air through all endoscope channels for a specified period of time and pressure according to the endoscope manufacturer's written IFU. Research has demonstrated that a minimum 10-minute dry time is effective in drying the channels and should be implemented (Alfa, 1991 [53]; Ofstead, 2018 [242]; Barakat, 2019 [79]) (see Annex K). The exterior of the endoscope and removable endoscope parts are dried using unused, clean, or sterile non-linting cloths. Complete drying to thoroughly remove all residual fluid after high-level disinfection is necessary to prevent the growth of gram-negative bacteria and other potential pathogens.

Drying should be completed outside of the AER, even when the AER has an air purge or extended dry time feature.

Drying can be facilitated by use of a preliminary flush of 70 % to 90 % ethyl or isopropyl alcohol. Isopropyl alcohol is considered a fixative. If the use of alcohol is a consideration, a multidisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel should conduct a risk assessment to determine whether endoscope lumens should be flushed with 70 % to 90 % ethyl or isopropyl alcohol (Costa et al., 2017 [125]).

The procedure for manual drying is as follows:

a) Use pressure-regulated instrument air or HEPA-filtered air to dry the channels in accordance with the manufacturer's written IFU (Ofstead, 2018 [242]; Barakat, 2019 [79]). An assortment of adapters can be needed to accommodate various size lumens, depending on the configuration of the drying device. The use of syringes or a handheld compressed air gun to dry the channels is not recommended, even if their use is specified in the endoscope labelling.

    1) Refer to the endoscope manufacturer's written IFU for guidance on correlating the force of air pressure to channel size and select the air pressure accordingly.

    2) Use the instrument air until no visible signs of moisture remain (or as recommended by the endoscope manufacturer). See Annex K for more information about methods to assess the efficacy of drying.

b) Thoroughly dry endoscope exterior and all removable endoscope parts with a clean, non-linting cloth. Ensure that crevices (for example at the control knobs) are dry. Pressure-regulated instrument air or HEPA-filtered air may be directed at crevices to facilitate drying of these hard to reach endoscope areas.

c) To reduce the risk of trapping liquid inside the endoscope, do not attach accessories (such as valves) to the endoscope during storage.

d) The healthcare facility should assemble an interdisciplinary team that includes infection preventionists, endoscopy and perioperative RNs, endoscopy processing personnel, endoscopists, and other involved personnel to determine the methods that will be used (see Annex K).

The endoscope should be dried promptly after every reprocessing cycle. This means that the endoscope should be dried whether the endoscope is intended for immediate patient use or for storage (Rutala and Weber, 2016 [281]; Petersen et al., 2017 [255]), with the exception of liquid chemically sterilized endoscopes that are used immediately.

8.3 Terminal sterilization by gaseous or vaporized chemical sterilization processes

8.3.1 General considerations

With the infection risk that endoscopes present to the patient, sterilization is the preferred method of microbial inactivation and the only option for instruments to be used in "critical" uses entering sterile body cavities, tissues, or vascular spaces. Sterilization continues to be recommended for endoscopes. Terminal sterilization is also required for all endoscope accessories that penetrate the mucosa, such as biopsy forceps, sphincterotomes, etc. When sterilization is required, most endoscopes require low temperature sterilization. Compatibility with low-temperature sterilization processes varies with endoscope make and model. Compatible processes can include ethylene oxide (EO), hydrogen

peroxide with or without plasma phase, and hydrogen peroxide-ozone sterilization systems, provided that the endoscope and/or sterilizer manufacturer has performed validated efficacy and compatibility testing and recommends in the written IFU or official documentation. Steam sterilization is often not compatible with flexible and semi-rigid endoscopes but can be used when the endoscope manufacturer's written IFU provides data showing compatibility with steam processes.

Successfully sterilized endoscopes can provide an increased safety margin over high-level disinfected endoscopes. Terminally sterilized endoscopes are rendered completely dry, packaged (which reduces the chance of contamination for longer periods of time), and are patient-ready. Packaged endoscopes have tamper-evident seals that clearly distinguish "used" endoscopes from "patient-ready" endoscopes."

This section outlines special considerations for the terminal sterilization of flexible and semi-rigid endoscopes using gaseous or vaporized chemical sterilization processes. The primary sources of information about terminal sterilization of endoscopes are the FDA-cleared labeling and the written IFUs of the endoscope and/or sterilizer manufacturers. Users should use FDA-cleared sterilization packaging products and other accessories for the selected specific sterilization type.

8.3.2 Packaging for terminal sterilization

8.3.2.1 General considerations

It is important to select sterilization packaging that allows for sterilant penetration through the packaging and onto and into the endoscope that maintains sterility and allows for aseptic presentation. Many types of packaging are available for gaseous and vapor chemical sterilization, including Tyvek® sterilization pouches, nonwoven textile sterilization wrap material, and rigid sterilization containers that maintain sterility. Select a product that is FDA-cleared and specifically labeled by its manufacturer for use in the intended sterilization method and the specific sterilizer model/cycle to be used.

Follow the endoscope manufacturer's written IFU for the method of sterilization, the packaging, and preparation for sterilization (e.g., how to stabilize the endoscope on a tray, use of vent caps).

If there are inconsistencies between the endoscope, sterilizer, and packaging manufacturers' written IFU, the manufacturers should be consulted to determine the appropriate processes before proceeding. Additional information on sterilization packaging is in ANSI/AAMI ST58 [14].

8.3.2.2 Sterilization pouches

Only sterilization pouches that are FDA-cleared and labelled as appropriate for use with the selected sterilization method should be used. When using sterilization pouches, the pouch manufacturer's written IFU should be followed.

Sterilization pouches should be large enough to contain the endoscope component or accessories without crowding, twisting, or tightly coiling the endoscope.

If double pouching will be used, the user shall confirm that double pouching has been validated by the endoscope manufacturer and the sterilization pouch manufacturer. The pouch manufacturer's written IFU for packaging items using double pouching should be followed. If the accessories or components are to be packaged in double pouches, two sequentially sized pouches should be used, and the sealed inner pouch should fit inside the outer pouch without folding.

8.3.2.3 Sterilization wraps

Only sterilization wraps that are FDA-cleared and labelled as appropriate for use with the selected sterilization method, sterilizer model and cycle, and lumen dimension (when available) should be used. Do not exceed the maximum wrapped package content weight as documented in the sterilization wrap manufacturer's written IFU for the specified sterilization method.

When using sterilization wraps, the wrap manufacturer's written IFU should be followed. The wrap manufacturer should be contacted if additional information is needed regarding wrap compatibility with the proposed sterilization method or load characteristics.

The user should follow the recommended wrapping procedures outlined in ANSI/AAMI ST79 [17].

Rationale: Wrap material selected for sterilization is labeled for the sterilization method, sterilizer model and cycle, and load characteristics (e.g., lumen dimensions) for which it has been shown to be effective. Some sterilization wraps contain cellulose and are contraindicated for use in hydrogen peroxide gas and hydrogen peroxide–ozone sterilization processes.

8.3.2.4 Rigid sterilization containment systems

Only rigid sterilization containment systems that are FDA-cleared and labelled as appropriate for use with the selected sterilization method, sterilizer model and cycle, and lumen dimension (when available) should be used. Do not exceed the maximum load weight as indicated in the rigid sterilization containment system manufacturer's written IFU for the specified sterilization method.

When using reusable containment devices (e.g., organizing trays cases, cassettes), the endoscope, sterilizer, and containment device manufacturers' written IFU should be followed. When using cases or cassettes intended to be used in conjunction with other packaging for terminal sterilization, appropriate terminal sterilization packaging should be selected in accordance with the containment device and sterilizer manufacturers' written IFU.

When using rigid sterilization containers with prepositioning bracketing or organizing tray inserts, the containers should be loaded in the sterilizer in accordance with the container and sterilizer manufacturers' written IFU.

When using rigid sterilization container systems, appropriate accessories such as filters should be used in accordance with the containment system and sterilizer manufacturers' written IFU.

Rigid sterilization container systems should be cleaned before sterilization, either manually or mechanically, according to the container system manufacturer's written IFU and by personnel following accepted practices for decontamination and employee safety, including PPE.

8.3.3 Terminal sterilization procedures

The general procedure for a terminal sterilization process is as follows:

a) Following point of use treatment, the endoscope and accessories should be cleaned, thoroughly dried, inspected (see 7.8), verified to be clean by a verification test as applicable (see 13.5.3 and F.3), and prepared for sterilization according to the endoscope manufacturer's written IFU. For low-temperature gaseous and vaporized chemical sterilization methods, vent caps may be required by the endoscope manufacturer to help protect the endoscope from damage due to pressure changes during the sterilization cycle.

b) Package the endoscope in compatible organizing trays and packaging for the specific endoscope and terminal sterilization process. Ensure that the venting cap is attached when indicated by the endoscope and/or sterilizer manufacturer's written IFU. Refer to the endoscope, packaging, and sterilizer manufacturers' written IFU.

c) Place a chemical indicator specific to the sterilization process selected in each package. A process indicator should be visible on the outside of the package or container (see 13.8.2). External chemical indicators (CIs) should be Type 1. Internal chemical indicators should be Type 3 or Type 4 but preferably Type 4 because these types of CIs provide the user with more information on the critical hydrogen peroxide sterilization parameters.

NOTE For steam sterilization of compatible endoscopes and accessories, see ANSI/AAMI ST79 [17].

d) Label each package with the lot code (see 13.3).

e) Document all items in the load (see 13.4.1).

f) Load the sterilization chamber as described in the endoscope and/or sterilizer manufacturers' written IFU.

g) Place a BI in a process challenge device (PCD) in the load as recommended by the sterilizer manufacturer's written IFU or use another FDA-cleared BI PCD labelled for the process and cycle (see 13.3).

h) Select the correct cycle.

i) When the cycle is complete, verify that the sterilization cycle parameters have been met and remove the load. Verify that external process indicators have reached their endpoint response (see 13.4.1).

j) Retrieve and incubate the BI in accordance with the manufacturer's written IFU and record the results (see 13.4.1).

k) Review all quality control and monitoring documentation.

l) Release load according to the health care facility policy.

8.3.4 Ethylene oxide gas sterilization

Ethylene oxide sterilization may be used for terminal sterilization of flexible and semi-rigid endoscopes when validated by the endoscope and/or sterilizer manufacturer and as described in the written IFU or documentation.

The endoscope and sterilizer manufacturers' written IFU, or documentation should be followed for cleaning, drying, and preparing the endoscope and its accessories for EO sterilization. The user should ensure that all water has been removed from the endoscope before sterilization. To aid in preparation of devices prior to sterilization, instrument air should be used to remove water from lumens or constricted areas. Channels should be dried for a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air. Consult the endoscope manufacturer's written IFU for maximum pressure (psi). If after 10-minutes of drying moisture is still observed, extend drying time until no moisture is visible. Thoroughly dry with a non-linting cloth all removable endoscope parts. A drying cabinet may also be used to aid in the drying of devices prior to packaging and sterilization.

A venting method and/or removal of the soaking cap before sterilization may be indicated in the endoscope manufacturer or sterilizer manufacturer's written IFU.

The packaging manufacturer's written IFU should be followed, and the manufacturer contacted if additional information is needed regarding packaging materials' compatibility with the EO sterilization method or load characteristics.

Acceptable packaging materials may include:

a) polyethylene plastic bags (designed for use as a sterile package and not more than 5 mm thick);

b) peel pouches made of spun-bonded olefin (Tyvek®), polyethylene-polyester laminate, paper/polyethylene-polyester laminate, or paper/polypropylene-polyester laminate;

c) woven textile, nonwoven textile paper, coated and uncoated wraps;

d) rigid sterilization container systems; and

e) plastic trays with paper or Tyvek® lids.

The EO sterilizer should be loaded in accordance with the sterilizer manufacturer's written IFU.

A single-chamber process for EO sterilization and aeration should be used in accordance with EPA regulations (EPA, 2008) [318]. Endoscopes should not be unloaded from the EO sterilizer until the aeration cycle is complete.

The requirements of the OSHA Ethylene Oxide Standard (29 CFR 1910.1047 [232]) must be followed, and a copy of the standard should be readily available.

For additional information, the user should consult the EO Safety Data Sheet and ANSI/AAMI ST41 [12]. See also H.7.

8.3.5 Hydrogen peroxide and hydrogen peroxide–ozone sterilization

Hydrogen peroxide and hydrogen peroxide–ozone sterilization may be used for terminal sterilization of flexible and semi-rigid endoscopes when validated by the endoscope and/or sterilizer manufacturer and as described in the written IFU or documentation.

The endoscope and sterilizer manufacturers' written IFU, or documentation should be followed to ensure that the endoscope can be successfully sterilized in the hydrogen peroxide or hydrogen peroxide-ozone sterilizer. The FDA-cleared sterilizer's labelling will indicate the types of materials and the lengths and diameters of lumens that can be successfully sterilized and other factors that will have an impact on successful sterilization.

The endoscope and accessories should be cleaned, dried, and prepared for sterilization according to the endoscope and sterilizer manufacturers' written IFU.

a) The user should ensure that all water has been removed from the endoscope before sterilization. To aid in preparation of devices prior to sterilization, instrument air should be used to remove water from lumens or constricted areas. Channels should be dried for a minimum of 10-minutes with pressure-regulated forced instrument air or a minimum of HEPA-filtered air. Consult the endoscope manufacturer's written IFU for maximum pressure (psi). If after 10-minutes of drying moisture is still observed, extend drying time until no moisture is visible. Thoroughly dry with a non-linting cloth all removable endoscope parts. A drying cabinet may also be used to aid in the drying of devices prior to packaging and sterilization.

b) A venting method and/or removal of the soaking cap before sterilization may be indicated in the endoscope manufacturer's written IFU.

The packaging manufacturer's written IFU should be followed, and the manufacturer contacted if additional information is needed regarding packaging materials compatibility with the hydrogen peroxide or hydrogen peroxide–ozone sterilization method or load characteristics.

Acceptable packaging materials may include:

a) non-cellulose based peel pouches;

b) polypropylene wrap; and

c) rigid sterilization container systems cleared for use in the specific type of hydrogen peroxide or hydrogen peroxide–ozone sterilizer.

The hydrogen peroxide or hydrogen peroxide-ozone sterilizer should be loaded in accordance with the sterilizer manufacturer's written IFU. Do not exceed the maximum chamber loading weight limit specified in the sterilizer manufacturer's FDA clearance and IFU for each type of sterilization cycle. Inadequate drying of the load prior to sterilization could lead to hydrogen peroxide and/or water droplets remaining following the cycle. ANSI/AAMI ST58 [14] recommends wearing chemical-resistant gloves when unloading the sterilizer. The package should be inspected for any signs of moisture.

OSHA permissible exposure limits apply to hydrogen peroxide and ozone (29 CFR 1910.1000, Table Z-1) [227]. For additional information, the user should consult the hydrogen peroxide and hydrogen peroxide–ozone sterilant Safety Data Sheet and ANSI/AAMI ST58 [14]. See also H.5 for hydrogen peroxide sterilization and H.6 for hydrogen peroxide-ozone sterilization.

Rationale: The rationale for the drying recommendations is that residual water droplets have the potential to cause residual chemicals to be present in a liquid form at the conclusion of the sterilization cycle, which can cause exposure to the chemical. Excess moisture can also cause the cycle to fail and the sterilizer to abort.

9 Sterile endoscope sheaths used as protective microbial barriers

Endoscope sheaths are available and FDA-cleared for use only with specified endoscopes (Ofstead, 2019 [234]). For all sheaths, after disposal of the single-use sheath, the endoscope should be thoroughly cleaned and high-level disinfected or sterilized according to the endoscope manufacturer's written IFU. The IFU for some of the cleared devices recommend alternative processing instructions to conventional liquid chemical sterilization/high-level disinfection when the sheath remains intact after endoscope use. For these endoscopes and sheaths, the endoscope and sheath manufacturers' written IFU should be followed (AORN, 2018 [367]). If the processing instructions from the endoscope manufacturer and the endoscope sheath manufacturer appear to differ or to conflict, health care facility personnel should contact each manufacturer to request additional information and make their own decision, in conjunction with an infection preventionist, based on all available information.

Endoscope sheaths may fall into two categories: sheaths that are intended to *reduce* the level of soiling of the endoscope (but the presence of the sheath does not impact the reprocessing procedures), and sheaths that are intended to *prevent* endoscope soiling and thus serve as microbial barriers (such that visually intact sheaths after use may allow for reduced reprocessing procedures of the endoscope). Endoscope sheaths may be used as an accessory device in conjunction with laryngoscopes, cystoscopes, esophagoscopes, bronchoscopes, and nasopharyngoscopes. The sheath is installed over the endoscope's insertion tube and might contain working channels through which irrigation, suction, and/or accessory equipment can be used.

10 Processing of endoscope accessories

10.1 General considerations

Processing certain reusable endoscope components, such as air/water and suction valves, biopsy port covers, water bottles, and tubing, requires the same level of inspection, cleaning, and high-level disinfection or sterilization as the endoscopes themselves. If compatible, valves should be subjected to sterilization (see 7.5.2). Alternatively, valves may be immersed in an LCS/HLD solution, following the manufacturer's written IFU, or single-use, disposable valves can be used.

Reusable endoscopic accessories that break the mucosal barrier (e.g., biopsy forceps, other cutting instruments) should be manually or mechanically cleaned as directed by the manufacturer's written IFU and then sterilized between each patient use (high-level disinfection is not recommended).

10.2 Procedure

The general procedure for processing endoscope accessories is as follows:

a) Remove all detachable parts from the endoscope and clean them individually prior to further processing.

NOTE For options for processing and tracking valves, see 7.5.2.

b) Open or disassemble the endoscope components, completely immerse them in a compatible cleaning solution, and clean them according to the manufacturer's written IFU.

c) Continue to brush and flush the valves until no visible soil remains.

d) Rinse open components with copious amounts of utility water until all cleaning solution is visibly removed.

e) Dry the accessories in accordance with the manufacturer's written IFU.

f) Immerse the valves in HLD solution, following the manufacturer's written IFU for disinfectant contact time and temperature for manual processes.

g) Rinse with specified water quality and repeatedly actuate valves during rinsing.

h) Alternately, valves can be disinfected in an AER cleared for processing of valves or sterilized. Follow AER manufacturer's written IFU or the sterilization recommendations from the valve and/or sterilizer manufacturer. Only those accessories validated for processing in the specific AER should be processed with that AER.

11 Storage of processed endoscopes

11.1 General considerations

Effective storage of flexible and semi-rigid endoscopes is an important aspect of processing to ensure the devices are safe for patient use because it helps provide protection of the endoscopes and accessories and prevents recontamination of the devices. Identification of patient-ready endoscopes is important because it distinguishes LCS/HLD processed endoscopes from non-processed endoscopes.

Methods that employ active drying of endoscopes with filtered air are the preferred means of drying the internal channels of endoscopes after processing. Storage cabinets are used to secure and, in some cases, circulate air through the processed endoscopes.

There is no consensus on the maximum storage time that should be allowed for a high-level disinfected endoscope. After completion of a LCS processing cycle, critical endoscopes should be used immediately; semi-critical endoscopes should be used immediately or handled and stored in a manner similar to that of high-level disinfected endoscopes.

11.2 Storage of high-level disinfected or liquid chemically sterilized endoscopes

11.2.1 Storage procedures

Endoscopes are to be stored in an area that is clean, well-ventilated, and dust-free in order to keep the endoscopes dry and prevent exposure to potentially hazardous microbial contamination. They should be stored in a manner that will protect them from damage or contamination and in accordance with the endoscope and storage cabinet manufacturers' written IFU.

Before storage, the channels of the high-level disinfected endoscope should be dry to help prevent bacterial growth and the formation of biofilm (see 8.2.5). If a drying cabinet is not used, dryness can be checked by using dryness indicators.

Endoscopes should be stored suspended vertically or horizontally in a cabinet designed for storage in a way to allow circulation of air in accordance with the endoscope manufacturer's written IFU (e.g., pressure of air flow through channels, diameter of endoscope coil). When high-level disinfected or liquid chemically sterilized endoscopes are stored vertically, the insertion tube should be as straight as possible, with the distal tip hanging freely.

All valves and other accessories shall be removed in preparation for drying and during storage. A tip protector that is made of material that can retain moisture (e.g., sponge) can create an environment favorable for microbial growth. Tip protectors should not cover the opening of the tip. Tip protectors are meant to be single-use unless otherwise specified in the manufacturer's written IFU. Reusable endoscope parts may be stored dry in a containment device designed and intended for this purpose (see 7.5).

See 7.5 for processing options for reusable detachable parts. The devices and valves should be dry prior to being placed in a storage cabinet. Valves should be dried according to the manufacturer's written IFU.

If the endoscope has angulation locks or a flexibility adjuster, it should be stored according to the IFU.

There should be sufficient space between and around endoscopes to prevent them hitting one another, which can cause damage to the endoscopes.

All critical devices (e.g., ureteroscopes, bronchoscopes) not used immediately should be processed again before use. Endoscopes should not be left in the AER basin for extended amounts of time (e.g., more than one hour), otherwise the endoscope should be reprocessed through high level disinfection/liquid chemical sterilization process prior to storage or immediate clinical use. This section provides available information that can be used by health care facilities to determine maximum storage time.

Rationale: When flexible and semi-rigid endoscopes are hung in the vertical position, coiling or kinking is prevented. Following recommended storage practices facilitates drying and decreases the potential for contamination.

11.2.2 Storage cabinets

Two types of storage cabinets for HLD-processed endoscopes are currently available: drying cabinets and conventional cabinets. There is no clear consensus at this time among professional organizations as to which type of cabinet is best; however, drying cabinets have been shown in scientific studies to reduce the risk of retained moisture and microbial contamination (Perumpail, 2019 [254]; Saliou, 2015 [284]) (see Annex K). Endoscopes hung in HEPA-filtered storage cabinets that do not have drying capabilities need to be dried prior to storage. Both cabinets are designed to store endoscopes (with or without channels) in a controlled environment. Neither cabinet type is designed to clean and/or disinfect endoscopes (BS EN 16442 [47]).

Endoscopes processed with HLD or LCS should be stored in a cabinet that is of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without any components touching the bottom of the cabinet, or the cabinet should be designed and intended by the manufacturer for horizontal storage of flexible endoscopes (CDC, 2017 [108]).

Cabinets used for storage of flexible endoscopes should be situated in a secure location such as in the clean workroom of the endoscopy processing room in a two-room design or in a separate clean area close to, but not within, the endoscopy procedure room (AORN, 2018e, IX.a [39]). Situating the storage cabinet in a secure location helps protect inventories of flexible endoscopes and supplies that are vulnerable to misappropriation. Locating the storage cabinet in the clean workroom or in a clean area outside of the procedure room helps prevent contamination of processed endoscopes. Storage cabinets should have doors and be located at least 3 ft (0.9 m) from any sink. Ensuring that storage cabinets have doors and are separated from sinks by at least 3 ft (0.9 m) provides protection and reduces the potential for processed flexible endoscopes to be contaminated by water droplets (AORN, 2018e [39]). Cabinets should remain closed to protect the integrity of the disinfected endoscope.

Cabinets and endoscopes shall be visually inspected to ensure cleanliness when the endoscope is placed into the storage cabinet and also when the endoscope is removed for patient use. An endoscope that is removed from a visibly dirty cabinet or is not dry shall be processed before use (SGNA, 2018 [297]). Storage cabinets should be cleaned in accordance with the manufacturer's IFU, or at least weekly and when visibly soiled.

Rationale: Johnston et al., (2019) [185] found bioburden on the face shields of endoscopists and on face shields fastened more than 6 feet away from the procedure area, which indicates that anything stored in the procedure room may become contaminated.

11.2.2.1 Endoscope drying cabinets

Endoscope drying cabinets are closed cabinets designed for storage of flexible endoscopes that circulate HEPA-filtered or instrument air through the cabinet and each endoscope channel at continuous positive pressure. The collective evidence shows that drying cabinets provide effective storage of flexible endoscopes to facilitate drying, decrease the potential for contamination, and provide protection from environmental contaminants (AORN, 2018 [367]). Within the drying cabinet, internal and external surfaces of the endoscope are intermittently or continuously dried, suppressing microbial growth. Studies related to the efficacy of drying cabinets compared with other methods of storage showed that drying cabinets effectively limited bacterial proliferation during storage of potentially incompletely dried endoscopes (Saliou, 2015 [284]; Perumpail, 2019 [254]).

Drying cabinets should be used in accordance with the drying cabinet manufacturer's IFU. See Annex K.

11.2.2.2 Conventional drying cabinets

Conventional cabinets are closed cabinets that enable circulation of HEPA-filtered or instrument air through the cabinet at passively or via continuous positive pressure, but do not include forced air through endoscope channels. When drying cabinets are not available, conventional cabinets may be used. Conventional cabinets should be cleaned in accordance with the manufacturer's IFU, at least weekly and when visibly soiled.

At a minimum, conventional cabinets with HEPA filtration should be used to store flexible endoscopes. When conventional cabinets are used, the facility should monitor for indications that the endoscope channels are not being dried before placement in the cabinet (results of drying verification tests (see Annex K), drip marks in the bottom of the

cabinet, etc.). If indications are noted, additional efforts should be taken to ensure drying (such as a drying time longer than 10-minutes, see 8.2.5.2 and Annex K).

Storage cabinets, unless modified to provide drying, or upgraded in accordance with a third-party drying manufacturer's IFU and approved by the storage cabinet manufacturer, do not meet criteria to be a drying cabinet.

If manual drying is used (see 8.2.5.2), verify the endoscope is dry per your health care facility's policy (see Annex K).

11.2.3 Identification of endoscopes during storage

Protocols should be developed to help ensure that users can readily identify an endoscope that has been processed and is ready for patient use.

The user should perform hand hygiene and don new, clean, non-latex gloves, according to the facility's policy, when handling processed endoscopes.

Before it is placed in the storage cabinet, a label or tag should be attached to the processed endoscope that includes:

a) the processing date;

b) the name(s) of the person(s) who performed the processing, optionally as specified by facility policy; and

c) expiration date, based on facility's established risk assessment, if applicable.

Rationale: The CDC recommends that a policy and procedure be developed to ensure that end users know whether a particular endoscope has been processed, because when an endoscope is left on a cart or other surface, the status of the endoscope (i.e., used, or unused) might not be clear (CDC, 2017 [108]).

11.2.4 Maximum safe storage time for high-level disinfected endoscopes

11.2.4.1 General considerations

The accepted maximum safe storage time (previously referred to as "hang time" or shelf life) for processed endoscopes before they can no longer be considered safe for patient use is not well defined. There are a limited number of studies addressing this issue. The available data suggest that the risk of contamination is reduced when storage is performed according to the endoscope and storage cabinet manufacturers' written IFU. Multiple studies support the concept of viable but non-culturable cells that persist through disinfection and remain following extended storage (Cholley et al., 2020 [118]; Perumpail et al., 2019 [254]; Alfa et al., 2017 [61]). If bioburden is not eliminated prior to storage, it may become more resilient over time and continue to grow, especially if the endoscopes are stored before being completely dry.

11.2.4.2 Risk assessment

A multidisciplinary team that can include infection preventionists, endoscopy RNs, endoscopy processing personnel, endoscopists, risk management, and other involved personnel should conduct a risk assessment to determine the maximum storage time for an endoscope before it should be reprocessed (AORN, 2018e, IX.h [39]). A number of guidelines and recommended practices provide recommendations as to the maximum duration of storage time before the endoscope should be processed prior to the next use (SGNA, 2018 [297]; VA, 2014 [131]; Infection Control In Endoscopy, 2011; West Coast District Health Board, New Zealand, reviewed February 2013; Canadian Standards Association, 2008; NHS National Services Scotland, 2004, amended Sep 2007; Health Service Executive Standards and Recommended Practices for Endoscope Reprocessing Units). It is recommended that facilities research the current literature (see Annex J). Due to the lack of consensus and evidence on the storage time, it is recommended that the health care facility conduct a risk assessment to determine the maximum storage time for an endoscope before it needs to be processed for use on the next patient. Items for consideration in the risk assessment include:

a) complexity and type of endoscope (e.g., lumened or non-lumened);

b) condition of the endoscope after processing (e.g., dry, or wet; flushed with alcohol prior to storage, instrument air purged);

c) the results and trends of the cleaning verification tests, when conducted;

d) staff competencies and compliance with facility policies and procedures;

e) method of transporting the endoscope from processing to storage (use of fresh/clean gloves, removal of the endoscope in a clean environment, whether aseptic technique was used to remove the endoscope from the AER, and whether the gloves and gown worn by personnel placing the endoscope in the AER were changed before removal);

f) conditions of storage environment (e.g., air-filtered or not air-filtered, temperature and humidity conditions, restricted access location);

g) if available, cabinet manufacturer test data on the length of time that the cabinet can store endoscopes without additional microbial growth;

h) excess handling during storage;

i) manufacturer's written IFU for storage;

j) compliance with professional organization guidelines for storage;

k) relevant research studies;

l) protective devices used to prevent contamination;

m) frequency of use;

n) patient population;

o) frequency, type, and results and trends of quality monitoring of processing;

p) quality of the final rinse water (see AAMI TIR34 [23]); and

q) criticality of the endoscope's intended clinical use.

Based on the results of the risk assessment, the health care facility should develop policies and procedures to address the maximum endoscope storage time. Compliance should be audited to determine if changes to storage time need to be made. The facility should define circumstances or conditions that could occur during storage that would mean that an endoscope should be processed before use on the next patient (e.g., likely contamination with a water source, contact with surrounding environment).

Health care facilities should address cases where processing is to be done when the established maximum storage time has been exceeded (i.e., immediate processing or processing before the next patient use). Currently, there are limited data to give a definitive answer as to best practices for this question. Health care facilities should consider the potential risks and benefits associated with increased processing, including additional wear on the endoscopes.

11.2.5 Storage of liquid chemically sterilized endoscopes

Liquid chemically sterilized endoscopes intended to be used as critical devices should be used immediately after processing. They may also be used immediately in semi-critical applications. If liquid chemically sterilized but not meant for immediate use, follow instructions for storage of high-level disinfected endoscopes. (See Annex J.)

11.3 Storage of terminally sterilized endoscopes and accessories

11.3.1 General considerations

Terminally sterilized endoscopes and accessories should be stored under controlled conditions in a manner that reduces the potential for contamination.

11.3.2 Storage area

Storage areas should be kept clean and dry. Sterile items should be:

a) stored far enough away from the floor, the ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, and compliance with local fire codes;

b) stored at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from outside walls;

c) stored in such a way that wrapped packages are not stored beneath rigid sterilization containers on the same shelf; and

d) positioned so that packages are not crushed, bent, compressed, or punctured and so that their sterility is not otherwise compromised.

Access to the sterile storage area should be restricted to authorized personnel.

Sterile endoscopes, including those packaged in rigid sterilization container systems, should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they could become wet.

Sterile endoscopes should not be stored on floors, on windowsills, or in areas other than designated shelving, counters, or carts.

The wrap manufacturer's IFU should be consulted for guidance on stacking trays. External shipping container and web-edged corrugated boxes should not be in the storage area.

Closed or covered cabinets are recommended for sterile storage. Open shelving may be used, but requires special attention to traffic control, area ventilation, and environmental services.

Shelving, carts, and bins used for sterile storage should be maintained organized, clean, and dry. The bottom shelf of storage carts or shelving should be solid. The shelving or carts should be designed for the weight and configuration of the load.

Steps should be taken to ensure that stock rotation occurs between all sterilized endoscopes.

Rationale: Adequate space is needed around sterile materials to allow for air circulation in the room, to prevent contamination during cleaning of floors, and to prevent contact between sterile items and the condensation that might form on the interior surfaces of outside walls. Also, fire codes specify minimum distances below the ceiling (usually 18 inches) to ensure the effectiveness of sprinkler systems (NFPA 13 [215], NFPA 99 [216]). Compression of packages can force air and microorganisms into the package contents, cause seals to burst, or puncture the packaging, all of which lead to contamination. Sterile endoscopes that become wet are considered contaminated because moisture brings with its microorganisms from the air and surfaces. Stacking can result in damage to the wrap caused by undue pressure from the weight. Closed cabinets limit dust accumulation, discourage handling, and minimize inadvertent contact with the stored items. External shipping containers and web-edged corrugated cardboard boxes can collect dust, debris, or insects during shipment and bring contaminants into the facility.

12 Transport of processed endoscopes

Immediately before removing the endoscope from the storage cabinet, the user should perform hand hygiene and don new, clean, non-latex gloves, according to the facility's policy, unless otherwise specified by the procedure or the endoscope manufacturer's written IFU.

During transport to the point of use, the endoscope should be identified as clean and protected from contamination and damage. Unless transported through a controlled, connected corridor, the endoscope should be loosely coiled and placed in a clean, covered, solid protective container that is nonporous, leak-proof on its sides and bottom, puncture-resistant, and large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.

The nonporous container may be a reusable container that shall be cleaned and disinfected between uses or a clean, single-use container. The container or liner should be visibly identified as clean.

Liquid chemically sterilized endoscopes that are to be used immediately in critical procedures should be transported within a closed processing container if one was used. If a closed processing container was not used, the endoscope should be removed using sterile gloves, transferred into a sterile bin, and covered with sterile drape. Use aseptic technique to avoid contaminating the device.

For endoscopes that are terminally sterilized for critical applications, transport the packaged endoscope within the sterile barrier system (see ANSI/AAMI/ISO 11607-1 [3] and ANSI/AAMI/ISO 11607-2 [4]).

Rationale: Disinfected and liquid chemically sterilized endoscopes can become recontaminated by hands and/or contact with surfaces while being handled and transported. Use of a barrier system can prevent recontamination. Recent research has demonstrated that soil and bioburden frequently remain on post-HLD, patient-ready endoscopes (Rex, 2017 [264]; Snyder, 2017 [293]; Bartles, 2018 [79]; Visrodia, 2014 [369]; Saliou, 2015 [282]; Ofstead, 2018a [245]; Ofstead, 2018b [240]). As such, gloves worn whenever handling endoscopes protects personnel and patients from exposure to contamination.

13 Quality control

13.1 General considerations

This section covers aspects of establishing policy and procedures, product identification and traceability, documentation and record-keeping, verification, and monitoring of the cleaning process, monitoring of high-level disinfection and sterilization processes, product recalls, and quality process improvement.

Quality control is a critical aspect of endoscope processing procedures. In all cases, manufacturers' written IFU, including those for the endoscope device, processing equipment, and other products used in processing, should be followed.

Quality control also includes verification and monitoring of personnel performance, work practices, and adherence to established policies and procedures.

13.2 Establishing policy and procedures for quality assurance and safety program

The health care facility should establish a multidisciplinary, comprehensive, written quality assurance and safety program for all aspects of endoscope processing. The program should include the following:

a) Identification of all personnel roles involved in endoscopy procedures, specifying their position descriptions and responsibilities.

b) Identification of all facility areas where endoscopes are used and processed.

c) Identification of all endoscopes, endoscope accessories, and endoscope processing equipment used in the facility, including manufacturer, model, serial number or facility-specific identification number, and unique device identifiers (UDIs).

d) Identification of the storage location, age, and status (e.g., maintenance schedule) of each endoscope.

e) Procedures for verification that the endoscopes and accessories used in the facility and new equipment are compatible with facility processing equipment and supplies based on the manufacturers' written IFU. If the labeling is unclear regarding compatibility, complete the risk assessment in accordance with Annex D.

f) Procedures for visual inspections and testing of the equipment and ancillary parts to identify conditions that could affect the cleaning or disinfecting processes (see 7.7 and Annex E).

g) Procedures for use of cleaning verification tests and recording results, if applicable.

h) Procedures for the use of microbial surveillance testing and recording results, if applicable.

i) Procedures for the use of process monitors as recommended by the AER, LCS/HLD, and sterilizer manufacturers and recording results.

j) Development and implementation of procedures that address specification evaluation, acquisition management, scheduled maintenance, and removal of equipment from use.

k) Verification and maintenance of records documenting that all manufacturer-recommended maintenance schedules and services are performed for all endoscopes and processing equipment (e.g., AERs and sterilizers) used in the facility.

l) Maintenance of records of the use of each endoscope, including model, serial number, and unique facility identifier or standardized UDI.

   — Records should document the patient upon whom the endoscope was used, the date and time of use, and the location of use.

   — Records should also show the system (model and serial number of the AER or sterilizer if applicable) used to process the endoscope and the identification of the person(s) responsible for processing the endoscope.

m) Assignment of personnel responsibilities for tracking the useful life of endoscopes and accessory equipment, including equipment and supplies for processing.

n) Audit and documentation of the introduction (and withdrawal from use) of all endoscopes, endoscope accessories, AERs, AER accessories such as endoscope connection devices, and sterilizers.

o) Establishment and documentation of education, training, and competency verification programs for all personnel responsible for processing endoscopy equipment and outline of schedules for periodic education and training updates and competency verification.

p) Establishment of procedures for storage of processed endoscopes prior to patient use.

q) Establishment of a method for detecting clusters of infections or suspected infections (i.e., pseudoinfections) associated with endoscopic procedures. If a cluster is suspected, the facility infection prevention staff should be contacted to complete case review and develop case definitions for the suspected infections. If it is confirmed or suspected to meet definition, the infections should be reported to appropriate risk management staff to report to the manufacturer of the endoscope and the endoscope accessories, the manufacturer of the chemical sterilant, sterilizer or AER, the FDA's MedWatch, and other relevant regulatory agencies. Facilities should develop a process for segregating and saving devices suspected of being defective for investigative purposes, Including, if possible, the packaging and identifying information such as lot or serial numbers.

r) Establishment of a procedure to investigate lapses in processing.

s) Availability of a spill kit capable of handling the maximum possible spill (see 8.2.2).

t) Procedures for the use of engineering controls such as exhausts, gas monitors, environmental controls (temperature, humidity, air flow) and records of equipment performance and maintenance as well as employee training as applicable.

13.3 Product identification and traceability

Each item or package intended for use should be traceable to a lot control identifier. The lot control identifier should designate:

a) the device name and identifier (e.g., serial number);

b) the identification number or code of the sterilizer, AER, or soaking container;

c) the date processing was completed;

d) the processing cycle number (if automated);

e) the patient identifier; and

f) the technician processing the device.

The health care facility's policy should determine when the lot control information is affixed to the package or correlated to the endoscope.

An instrument tracking system that provides endoscope traceability of the sterilizer's unique identifier and cycle and load number may be used in lieu of a sterilizer load label.

Lot control information should be documented and associated with the endoscope (e.g., via a logbook or electronic record).

Items that are processed for immediate use by means of a manual LCS/HLD soaking system require a means of identification of the items processed.

Rationale: Lot identification enables personnel to retrieve items in the event of a recall and to trace problems to their source. Quality control measures (e.g., the use of conventional BIs) might not yield results until after the processed load has been used. Quality control record-keeping is critical and relies heavily on historical data, especially where quality control measures yield conflicting evidence. Record-keeping is needed for both epidemiological tracking and ongoing assessment of the reliability of chemical sterilization and high-level disinfection processes.

13.4 Documentation and record-keeping

All recorded information may be incorporated into a paper log or preferably, an electronic record-keeping system or may be filed as individual documentation records. All records should be retained for a period of time not less than that specified by state or local statues and legal considerations (e.g., statues of limitations for lawsuits). If statutes are not specific, record retention should be determined by the facility's risks management personnel, legal counsel, and infection prevention and control personnel.

13.4.1 Documentation

1) For each processing cycle (including gaseous chemical sterilization, liquid chemical sterilization, or high level disinfection) the following information should be recorded and maintained:

    a) assigned lot or load number (see 13.3 for information on lot code for individual items) to include the gaseous chemical sterilizer, AER, LCSPS or soaking container identification, cycle number, and date and time of the cycle;

    b) identification of the operator;

c) description of specific items/contents in the lot or load, including quantity of each item, processing area;

d) name and/or unique patient identifier of the patient the endoscope was used in;

e) procedure, physician and the serial number or other identification of the endoscope; and

f) any results of microbial test of endoscopes or processing equipment.

2) In addition to point 1 - for LCS/HLD cycles this information should also be recorded and maintained, as applicable:

a) Shelf-life date. the lot number, and the date that the original container of LCS/HLD was opened, the use-life of the open container; the date that the product was activated or diluted; the date that the activated, diluted, or ready-to-use solution was poured into a secondary container; and the reuse-life of the solution;

b) Exposure time and temperature and other critical parameters, if not provided by the physical monitors on the AER;

c) LCS/HLD type and concentration; pH test results if required by the facility policy or the manufacturer's written IFU;

d) Results of MRC or MEC solution monitoring test or CI, as applicable;

1) Any reports MRC or MEC failure testing results or CI, as applicable;

2) See 8.2.4.1 for actions to take with failed test results;

e) LCS spore test strip results, if used, according to manufacturer's written IFU for the system manufacturer;

f) Results of quality control testing of MRC or MEC test or CI, as applicable, if indicated by the written manufacturer's IFU;

g) Results of recording chart, printout, or electronic recording of physical parameters of the AER. This data should be dated, and the operators should review and sign each cycle.

3) In addition to point 1 – for gaseous chemical sterilization cycles, this information should also be recorded and maintained:

a) results of BI and appropriate control according to BI manufacturer's written IFU;

b) results of CI used in internal pack and external exposure monitoring;

c) any reports of positive BI, negative BI control, or failed CI results (see 13.10.2 for actions to take with failed results); and

d) results of recording chart, printout, or electronic recording of physical parameters from the sterilizer. This data should be dated, and the operators should review and sign each cycle.

Other documentation should be recorded and maintained:

1) A record of repairs and preventative maintenance should be kept for each reprocessor or sterilizer or mechanical soaking equipment.

2) Date on any personnel exposure liquid or chemical sterilants. OSHA requires that individual employee exposure records should be kept for at least the duration of the employment.

a) For EO, OSHA requires that records be kept for the duration of employment plus 30 years.

Also consult federal, state, and local regulations.

Rationale: Documentation helps ensure monitoring of the process as it is occurring, verifies that critical cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether recalls are necessary and the extent of recalls, if evidence subsequent to lot release, such as a positive BI or spore test strip, nonresponsive CI, failed solution test strip, or chemical monitoring device suggests processing problems. Knowing the contents of the lot or load enables personnel to decide how critical a recall might be. Digitization of the process can allow quick access to load information, thus facilitating a quick response. In addition, this documentation provides evidence of a processing area's quality control program. Electronic records of process monitoring results, including specific load item identification, are recommended because of their better legibility, accuracy, traceability, security, and data integrity. The length of time to retain sterilization and/or HLD records depends on many different factors and may vary from facility to facility depending on policy and applicable regulations.

13.4.2 Expiration dating for terminally sterilized endoscopes

Each packaged item in a sterilization load should be labeled with a control date for stock rotation and the following statement (or its equivalent): “Contents sterile unless package is opened or damaged. Please check before using.” This information can be incorporated into the lot identification on the label or imprinted or affixed separately on the outside of the package. If the product contains material that degrades over time (e.g., latex), the product package should be labeled with a clearly identifiable expiration date that takes this degradation into account or is based on the device manufacturer’s written IFU. If a time-related shelf-life system is used, the product package should be labeled with an expiration date.

Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for stock rotation.

13.5 Verification and monitoring of the cleaning process

13.5.1 General Considerations

Satisfactory cleaning processes should reduce clinical soil to a level that allows the subsequent disinfection or sterilization process to be effective. Cleaning of flexible endoscopes is a challenging process due to the complex design and heavy bioburden that is commonly present after a patient procedure. Verification involves both visual inspection and the use of rapid cleaning verification indicators. Both are important as part of a comprehensive quality control program.

Visual inspection is greatly enhanced with the use of magnification and illumination. Visual inspection can include the use of borescopes to inspect the inner channels/lumens present in many flexible endoscopes (see Annex E).

Visual inspection alone is not able to determine if the reduction in clinical soil is sufficient for an effective cleaning result but is critical to determine any defects or potential damage to the endoscope.

Cleaning verification indicators provide an independent, objective assessment of the cleaning process. Benchmarks can be determined by the facility based on guidelines, independent research or information provided by the product manufacturer. Cleaning verification is also used for surgical instruments and environmental surfaces to assess the cleanliness of the item.

Proper rinsing in accordance with the manufacturers’ written IFU can help avoid potential residual detergent/disinfectant interference.

There are various markers that can be detected in clinical soil that can provide important information to the user, identify inadequate cleaning processes, and serve as a quality control tool.

Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process in removing or reducing to an acceptable level the clinical soil that occurs during the use of an endoscope. These types of indicators do not measure microbial contamination.

High-risk endoscopes (see 3.31) and/or those that are of complex design (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes and as determined by the facility) shall be monitored with cleaning verification tests after each cleaning. Manual cleaning of flexible endoscopes that are not determined to be high-risk should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed). See Annex F, particularly F.4, for statistical frequency determination.

It is not recommended to perform a cleaning monitor test after the AER cycle as these tests are meant to verify cleaning efficacy and do not measure microbial contamination.

Rationale: Visual inspection alone is not sufficient for assessing the efficacy of cleaning processes. The use of methods that are able to identify organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

13.5.2 Visual inspection after manual cleaning

Cleaning verification of flexible and semi-rigid endoscopes by users should include the following:

a) Visual inspection combined with other verification methods (see 13.5.3) that allow the assessment of both external surfaces and internal housing and channels. Visually inspect the distal ends of endoscopes using lighted magnification (e.g., 10x).

b) Testing of the cleaning efficacy of mechanical equipment.

c) Monitoring of key cleaning parameters (e.g., cleaning agent dose, temperature).

The endoscope should be visually inspected. If any damage is observed during or after the cleaning process, the device should be removed from service and evaluated for repair. See Section 14.

Tools such as video borescopes of an appropriate dimension (i.e., length and diameter) can be used to visually inspect the accessible internal channels and document their condition.

Several methods can be used to evaluate the results of the cleaning process. The most common is visual inspection. Careful visual inspection should be conducted to detect the presence of any residual soil. Inspection using magnification and additional illumination will identify residues and/or damage more readily than the unaided eye. Direct visual inspection is not possible for all inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, and biopsy forceps) without the use of special equipment (e.g., borescope). Not all residual contamination or microorganisms can be detected by visual inspection as they are not accessible to visual inspection. Further, residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean (Visrodia et al., 2014 [369]).

13.5.3 Cleaning verification tests for users

Cleaning verification tests are performed following cleaning and before disinfection or sterilization and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the clinical soil that occurs during the use of an endoscope.

Methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be implemented.

High-risk endoscopes (see 3.31) and/or those that are of complex design (e.g., duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes and as determined by the facility) shall be monitored with cleaning verification tests after each cleaning. Manual cleaning of flexible endoscopes that are not determined to be high-risk should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed). See Annex F, particularly F.4 for statistical frequency determination.

Annex F provides information related to user verification of cleaning procedures and cleaning equipment, including the currently available test methods that apply to in-use evaluation of, respectively, efficacy of cleaning of medical devices and efficacy of washer-disinfectors used for flexible and semi-rigid endoscope processing. An example of a cleaning verification program is also provided.

Several technologies are available that can be used to measure the levels of organic soil and microbial contamination on the cleaned device. The published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user: protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP), and an enzyme that detects specific bacteria (Alfa et al., 2012 [58]; Alfa et al., 2013 [36]; Alfa et al., 2014 [56]; Visrodia et al., 2014 [369]; Alfa, 2020 [63]).

Two basic components of user verification of cleaning efficacy are as follows:

a) Establishing a reasonable benchmark; this is the level of cleaning that can be achieved consistently using specific soil markers relevant to devices used for patients;

b) Using rapid, easy-to-perform methods that reliably demonstrate that the cleaning benchmarks have been achieved.

This testing should include, at a minimum, monitoring of the instrument/suction channel (ANSI/AAMI ST58 [14]).

Facilities should establish benchmarks based on their facility practices, types of endoscopes, types of equipment, training available, and cleaning verification test used. Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Check with specific cleaning verification test manufacturers' written IFU for their recommended benchmark or pass/fail threshold value. See F.2.

The benchmarks for residual soil and bioburden levels after cleaning might become more definitive as more data become available and/or more efficient cleaning methods are developed. Users should review current literature along with the manufacturer's data to formulate policies and procedures for verification of cleaning efficacy. A study has shown that some benchmarks can be significantly lowered due to the increase in cleaning efficacy achieved by automated pump-assisted cleaning (Alfa et al., 2014 [56]).

Some cleaning verification systems provide quantitative results that can be tracked and trended over time. Some systems additionally have record-keeping or data capture systems that can aid in identifying endoscopes with repeated failed cleaning results.

NOTE It is not recommended to perform a cleaning monitor test after the AER cycle as these tests are meant to verify cleaning efficacy.

Rationale: Visual inspection alone is not sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures.

13.5.4 Testing cleaning efficacy

The facility's quality assurance program should include ways to verify that the cleaning equipment is working and that the cleaning process is effective. Automated cleaning equipment should be tested upon installation, during routine use, and on all cycles used after repairs, and when changing to a new type of cleaning solution. The automated cleaning efficacy test and equipment manufacturer's written IFU should be followed.

When developing a user verification procedure for the cleaning process (see Annex F), processing personnel should ensure the following:

a) The endoscope manufacturer has provided a written IFU detailing the recommended cleaning process.

b) The facility has established, clarified, and documented a standard cleaning process for the device (see Section 7).

c) High-risk endoscopes (see 3.31) are monitored with cleaning verification tests after each use. Manual cleaning of flexible endoscopes that are not determined to be high-risk should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed) [see 7.8.4 and F.4].

d) Cleaning verification results are documented.

e) The facility has established, clarified, and documented a process to address cleaning verification failures and trends.

f) The facility has established an education, training, and competency assessment program that verifies that personnel are consistently achieving the expected level of cleaning.

Rationale: Meticulous manual cleaning is essential for the removal of organic contamination that can interfere with the subsequent disinfection or sterilization process. The manual cleaning step is prone to error (Dirlam-Langley, 2013 [135]; Ofstead, 2010 [245]; ASGE, 2017 [28]; Ofstead, 2015 [235]; Ofstead, 2016 [247]) and therefore should be monitored on a routine basis at least as frequently as is recommended for the cleaning equipment. Testing the equipment upon installation, during routine use and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness (AORN, 2018 [367]).

13.6 Monitoring of liquid chemical sterilization/high-level disinfection

13.6.1 Monitoring of manual processes

13.6.1.1 Physical monitors

Physical monitoring of manual liquid chemical sterilization/high-level disinfection processes using a thermometer and timer should be completed for each cycle. The results of physical monitoring should be documented (see 13.4.1).

The calibration of thermometers, timers, and other monitoring equipment should be verified periodically, according to facility policy.

A reusable HLD solution should be visually inspected before each use and discarded if precipitates (e.g., crystallization) or particulates are observed, even if the solution is within its use-life. The solution manufacturer's written IFU should be followed for specific guidance. The solution container should be covered. The contact time and temperature of LCS/HLD solutions should be documented.

If the interpretation of the physical monitors or visual inspection of the solution suggests inadequate processing, the items should not be dispensed or used. Follow-up measures should be initiated per facility policy.

Rationale: Physical monitoring is needed to help ensure that the parameters are correct for every cycle and to detect malfunctions as soon as possible so that corrective action can be taken. Calibrating thermometers and timers used for physical monitoring helps ensure accuracy and precision. Covering the solution container prevents evaporation of the solution and exposure to light, both of which can affect the efficacy of the chemical agent.

13.6.1.2 Solution test strips or chemical monitoring devices

13.6.1.2.1 General considerations

Solution test strips or chemical monitoring devices are designed to determine whether the concentration of the active ingredient in the LCS/HLD solution is at the MRC or MEC for the LCS/HLD for both manual and automated processes. These solution test strips, or chemical monitoring devices assist the user in determining when the solution should no longer be used. All solution test strips, or chemical monitoring devices should be used according to the manufacturer's written IFU.

Rationale: The manufacturer's written IFU provides information on the reliability, safety, and performance characteristics of the product.

13.6.1.2.2 Using solution test strips or chemical monitoring devices

Processing personnel should use the solution test strip or chemical monitoring device cleared by the FDA for use with the specific LCS/HLD product. The manufacturer's written IFU should provide information on the reliability, safety, and performance characteristics of the product, including the interpretation of the solution test strip or chemical monitoring device reaction, the MRC or MEC that the solution test strip or chemical monitoring device is designed to detect, and the shelf life and storage requirements. Any necessary quality control test of the solution test strip or chemical monitoring device should be performed according to their manufacturer's written IFU.

Rationale: Solution test strips or chemical monitoring devices are needed to detect inadequate concentration of the active ingredient of the LCS/HLD.

13.6.1.2.3 Frequency of use

The LCS/HLD solution should be tested before or during each use.

Rationale: The manufacturer's written IFU will identify a solution test strip or chemical monitoring device to be used with the product or a suitable FDA-cleared alternative. The concentration of an active ingredient in the LCS/HLD solution will decrease with dilution by water, the presence of organic or other extraneous materials, and exposure of the solution to light. Checking the concentration of the active ingredient before use can reduce the risk associated with use of an ineffective LCS/HLD solution.

13.6.1.2.4 Interpretation

Unless otherwise directed by the solution or equipment manufacturer, the solution test strip or chemical monitoring device shall be read before the LCS/HLD solution is used. Processing personnel should receive education, training, and complete competency verification regarding the performance characteristics of the solution test strip or chemical monitoring device to be used.

Users should follow the manufacturer's written IFU when interpreting solution test strips or chemical monitoring devices. If the interpretation suggests that the concentration of active ingredients is inadequate, the solution should be discarded even if it is within its use-life. Suppliers of solution test strips or chemical monitoring devices that change color often provide visual color interpretation reference charts. If available, these charts should be obtained and used for education of and referenced by processing personnel.

Color-blind testing should be done for all processing personnel to ensure that they will be able to compare the test strip results to the interpretation reference charts.

13.6.1.2.5 Inadequate processing

If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate and if items have been processed in this ineffective solution and used, the following actions should be taken to identify these items:

a) The supervisor or other designated person and the designated infection prevention and control personnel should be verbally notified immediately, and this notification should be followed by a written report. The report and notification should include:

   1) the time and date of the questionable processing cycles;

   2) a description of the soaking or processing container and the load, including lot control numbers, product and patient names, and other identifying information;

   3) the results of physical monitoring and the solution test strip or chemical monitoring device obtained from the user; and

   4) any other information that could be useful in determining whether the results of the solution test strip or chemical monitoring device are valid or questionable.

b) Items processed since the last cycle for which the solution test strip or chemical monitoring device indicated an adequate concentration should be considered unprocessed. They should be retrieved, if possible, and processed. The LCS/HLD solution in question should be discarded.

c) After the cause of the processing failure has been determined and addressed, the LCS/HLD solution should be tested with a solution test strip or chemical monitoring device. If the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate, the solution should be discarded and replaced with freshly prepared solution.

d) Determine whether a product recall is necessary. Refer to 13.12.

Rationale: Following the recommended protocol when the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate can provide valuable data in support of corrective actions and can aid in identifying potential improvements in work practices.

13.6.2 Monitoring of automated processes

13.6.2.1 General considerations

Process monitoring devices (such as spore test strips, solution test strips, or chemical monitoring devices) should be used to monitor the processing conditions in automated processing equipment that use LCSs/HLDs. The process monitoring devices defined by the manufacturer of the chemicals and/or processing equipment should be used and interpreted according to the manufacturer's written IFU.

Unless otherwise directed by the solution or equipment manufacturer, solution test strips and chemical monitoring devices should be used to test automated equipment before or during each use. The use and interpretation of these strips and chemical monitoring devices to monitor the concentration of active ingredients in LCS/HLD solutions are described in 13.6.2.2. Some AERs have built in mechanisms to monitor MEC/MRC and record the results.

Rationale: The devices to be used are determined by the written IFU from the manufacturer of the chemicals and/or automated processing equipment. Process monitoring devices might not be commercially available for all automated processes.

13.6.2.2 Use of physical monitors and process monitoring devices

Physical monitors reflect the parameters of the automated processing equipment and include displays, digital printouts, and gauges. Some processing systems include on-board diagnostics that enable the machine to perform routine physical self-testing. The user should obtain information from the manufacturer of the monitoring device regarding the accuracy and precision of the monitor, what parameters are measured, and any maintenance and/or calibration required to ensure the continued adequate performance of the equipment.

At the end of the cycle and before items are removed from the processing equipment, the operator should examine and interpret the printout to verify that cycle parameters were reviewed and met and should initial it to allow later identification of the operator. Automated processing equipment that does not have physical-monitor recording devices should not be used. Electronic software programs are also available that provide a real-time, paperless, permanent recording of physical parameters. Automated processing equipment without electronic data transfer, recording, or printing capabilities should not be used.

NOTE It is important that any chart or printout is readable.

If the interpretation of the physical monitors or process monitoring devices (such as spore test strips, solution test strips, or chemical monitoring devices) or visual inspection of the chemical solution, as defined by the manufacturer, suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the designated supervisor or delegated individual, who should initiate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the automated processing equipment cycle conditions and provides permanent records by means of chart recordings, digital printouts, or electronic records. Physical monitoring is needed to detect malfunctions as soon as possible so that corrective actions can be taken. Process

monitoring devices (such as spore test strips, solution test strips, or chemical monitoring devices) provide additional information about the effectiveness of the process and assist in determining the reasons for a process failure.

13.6.2.3 Automated processing equipment malfunction

If the physical-monitoring records or process monitoring devices (such as spore test strips, solution test strips, or chemical monitoring devices) indicate any malfunction or suspicious operation, the load shall be considered inadequately processed and should not be used. The processing equipment manufacturer's written IFU should be reviewed for troubleshooting information. After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the manufacturer's written IFU and the processing equipment removed from service. All items in the terminated cycle should be reprocessed. The health care facility engineer, or maintenance contract service personnel or technician should then be notified, and the malfunction should be corrected. Faulty processing equipment cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not sufficient.

Many liquid chemical sterilization/high-level disinfection automated processing equipment computer programs are designed to detect inadequate cycle conditions. Computer-controlled equipment will often abort the cycle when the required parameters for the process have not been met. Some automated equipment will also provide various types of alerts regarding equipment performance. Users of the equipment should be educated and trained to distinguish between alerts that represent fail conditions and those that do not, and what actions need to be taken to ensure adequate processing. Refer to the manufacturer's written IFU or documentation.

When repairs involve parts that are usually replaced under preventive maintenance procedures, verification of the processing equipment's operation to the manufacturer's specifications should be performed prior to returning the equipment to service.

Rationale: Altering the cycle parameters of malfunctioning processing equipment might not correct a problem. Adequate processing of future loads will be jeopardized if the processing equipment continues to be used without repair and requalification. To restore processing equipment to full performance, it is necessary to identify the exact cause of the malfunction.

13.6.2.4 Inadequate processing

If any process monitoring device (such as spore test strips, solution test strips, or chemical monitoring devices) defined for use with liquid chemical sterilization/high-level disinfection indicates the concentration of the active ingredients or specific process parameter during a cycle was inadequate, the actions described below should be taken to identify the reasons for this failure:

a) Follow the manufacturer's written IFU to troubleshoot the problem.

b) If troubleshooting was not successful, a description of the processing equipment failure should be included in a written report and notification to health care facility designated management.

c) Any processing equipment in question should be removed from service.

d) Unless otherwise indicated, infection prevention and control, sterile processing, and facility maintenance personnel should attempt to determine the cause of the processing failure.

e) After the cause of the processing failure has been determined and corrected, the complete processing system should be tested according to the manufacturer's written IFU, including any associated diagnostic cycles and/or testing with process monitoring devices (such as BIs, spore test strips, CIs, solution test strips, or chemical monitoring devices). If the physical-monitoring results and the process monitoring devices for the cycle are satisfactory, the processing equipment can be returned to service.

Rationale: Conducting the above protocol when the solution test strip or chemical monitoring device indicates that the concentration of the active ingredient is inadequate will provide valuable data in support of any corrective action required and potential improvements in work practices.

13.6.3 Microbiological surveillance of endoscopes

Contaminated endoscopes and failures in processing have been associated with outbreaks of health care-associated infections (Kovaleva et al., 2013 [202]; O'Horo et al., 2016 [224]; Kumarage, 2019 [203]; Sorbets, 2019 [300]). Many of these outbreaks have been investigated by the microbiological sampling of flexible endoscopes and/or associated equipment (such as AERs, water bottles and accessories). The use of microbiological surveillance testing of endoscopes as a quality assurance measure is advised in the processing guidelines of several international organizations, including the Gastroenterological Society of Australia (GESA), and the European Society of Gastrointestinal Endoscopy/European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGE/ESGENA) (Taylor et al., 2011 [308]; Beilenhoff et al., 2007 [89]). Recent investigations of Carbapenem-resistant Enterobacteriaceae (CRE) infections associated with endoscopes have also suggested the benefits of increased microbiological surveillance to reduce the risk of patient to patient microbial transmission associated with certain types of endoscopes (Galdys, 2019 [158]; Bourigault et al., 2018 [97]; Yang et al., 2017 [378]; Kovaleva et al., 2013 [202]; O'Horo et al., 2016 [224]; Ross et al., 2015 [270]). To date, in the USA, guidelines on the processing of flexible gastrointestinal endoscopes (ASGE, 2017 [29]; AORN, 2018e [40]; Petersen et al, 2017 [255]; SGNA, 2018 [297]) do not specifically recommend microbiological surveillance.

The FDA, CDC, and American Society for Microbiology (ASM) together with other experts released validated protocols for surveillance sampling and culturing of duodenoscopes ("Duodenoscope Surveillance Sampling and Culturing – Reducing the Risks of Infection," Department of Health and Human Services Collaboration, FDA, 2018 [345]). Although this protocol is specific to duodenoscopes, aspects of it may be applied to other types of flexible endoscopes. Although the use of this protocol is voluntary for health care facilities, sampling and culturing data can be used as part of an overall quality control program for endoscope processing. A recently published interim report by the FDA on mandated surveillance testing of duodenoscopes by manufacturers of those endoscopes found that 5.4 % have cultured positive for organisms of concern (FDA, 2019 [344]).

Conducting endoscope surveillance sampling and culturing is a time- and resource-intensive process (De Wolfe et al., 2019 [129]; Almario et al., 2015 [67]; Kohli et al., 2017 [198]). Although there are methods to assess the quality of the cleaning processes, such as ATP and other assays, those methods are not intended to be used after high-level disinfection or sterilization of medical devices. Two published studies evaluated the efficacy of a rapid test method for gram negative bacteria and did find this method proved to correlate with traditional culturing methods for detecting Gram negative bacteria (Alfa, 2020 [63], Washburn and Pietsch, 2018 [372]). Health care facilities should consider their own needs and available resources to implement this type of procedure (see FDA, 2018 [344]). Health care facilities that choose to implement surveillance sampling and culturing should be aware of the following:

a) The results of microbiological sampling cannot be used to verify that an endoscope is free of microbes or sterile.

b) Surveillance sampling should not be considered a replacement for a comprehensive quality assurance and safety program for all aspects of endoscope processing (13.1).

c) Endoscope surveillance sampling and culturing is a shared responsibility of multiple departments within a health care facility. Those departments should jointly:

    1) identify the necessary resources and training required to implement surveillance sampling and culturing of endoscopes;

    2) determine the specific procedures that will be implemented for surveillance sampling and culturing (e.g., each health care facility should determine the frequency of sampling, whether to release or quarantine endoscopes pending culturing results, and whether to perform additional endoscope processing procedures following sampling); and

    3) develop an action plan for culture results, which might range from actions such as review of processing procedures to endoscope removal and patient notification and follow-up.

The FDA/CDC/ASM protocol includes multiple options for different duodenoscope models and options for culturing techniques. Duodenoscopes should be sampled from the instrument channel, elevator recess, and elevator wire

channel (when accessible). The culturing process should include concentration of the sample (by filtration or centrifugation), followed by enrichment using non-selective bacterial media. The specified sampling procedure followed by filtration and plating has been validated and shown to extract most, but not all, microbes that were deposited on duodenoscopes. Health care facilities that choose to use this protocol should select the sampling and culturing options and develop the microbial limits and action plans that meet the needs of their site. More information is available at the FDA website.

Table 3—Microbiological culture surveillance sampling advantages and disadvantages*

Advantages	Disadvantages
— Advised in guidelines of several international organizations. — Monitor effectiveness and quality of processing. — In comparative studies, can provide feedback on efficacy of corrective interventions. — Can assist in detecting endoscopes requiring service. — Can help identify sources of contamination. — Can reduce risk of patient infection or pseudo-infection associated with endoscope reuse. — Can aid in the interpretation of results of clinical samples obtained by aspiration through an endoscope (e.g., is the patient sick or is the endoscope/clinical sample contaminated?).	— Not advised in current US guidelines. — Interpretation of data on low-concern organisms (e.g., non-pathogenic organisms or environmentals) is difficult as persistent levels can indicate a problem with processing or a problem with improper aseptic technique during endoscope sampling. — Does not culture viruses, fungi, or all bacteria of concern, resulting in false negative results. — False-positive and false-negative rates and limits of detection not established, and sensitivity of routine cultures might not be reliable for detecting organisms associated with outbreaks. — Negative culture does not guarantee that effective processing occurred. — If quarantine of endoscopes is specified until culture results have been obtained, does not allow for rapid reuse of endoscope, and could lead to delays in patient care. — Resource-intensive; requires additional expenses for testing and time for personnel to collect and process microbiological samples.

*NOTE Based on: Van Wicklin S. *Microbiological culture surveillance of flexible endoscopes: A systematic review. Canadian* Journal of Infection Control 31(2):79-84, 2016. [367]

13.7 Monitoring gaseous and vapor chemical sterilization processes

13.7.1 Physical monitors

Physical monitors include time, temperature, and pressure recorders, displays, digital printouts, and gauges. The user should obtain information from the manufacturer of the monitoring device certifying the accuracy and precision of the monitor and describing any maintenance required to ensure the continued adequate performance of the equipment.

For sterilizers with recording charts, the operator should ensure at the beginning of the cycle that the recording chart is marked with the correct date and the sterilizer number. For sterilizers, the operator should:

a) check to verify that the cycle identification number has been recorded and that the pen or printer is functioning;

b) at the end of the cycle and before items are removed from sterilizer, examine, and interpret the chart or printout to verify that cycle parameters were met;

c) initial the printed record to allow later identification of the operator;

d) ensure that the printed record is readable; and

e) retain documents as in 13.4.1.

Sterilizers should not be used without a means for record-keeping and cycle verification.

Most temperature sensors indicate temperature in the sterilizer chamber, not at the center of packs. Incorrect load configuration or package composition can interfere with air evacuation and sterilant penetration, conditions that will not be revealed in the temperature recording. Therefore, physical monitoring and other indicators of sterilizer performance should never be considered a substitute for careful adherence to prescribed packaging and loading procedures.

If the interpretation of the physical monitors suggests inadequate processing, the items should not be dispensed or used. The interpreter should inform the supervisor or delegated individual, who should initiate follow-up measures.

Rationale: Physical monitoring provides real-time assessment of the sterilization cycle conditions and provides permanent records by means of chart recordings or digital printouts. Physical monitoring is needed to detect malfunctions as soon as possible, so that corrective actions can be taken in the event of failures.

13.7.2 Gaseous and vaporized chemical sterilizer malfunction

If the physical-monitoring records indicate any malfunction or suspicious operation, the cycle load should be considered unsterile and not used. In addition, the following steps should be taken:

a) The supervisor or delegated individual should be notified.

b) The manufacturer's written IFU should be reviewed for troubleshooting information.

c) After examination, if the malfunction cannot be corrected immediately, the cycle should be terminated according to the sterilizer manufacturer's written IFU, and the sterilizer removed from service.

d) All wrappers and disposable products from the aborted cycles should be replaced, and new process indicators should be used.

e) The health care facility engineer, or maintenance contract service personnel should be notified, and the malfunction corrected.

A faulty sterilizer cannot be made operational without identifying and correcting the underlying problem; merely extending the cycle time, for example, is not sufficient. After a major repair of a sterilizer, it should be requalified according to the manufacturer's written IFU (see also ANSI/AAMI ST41 [12] and ANSI/AAMI ST58 [14]).

Users of the equipment should be educated and trained to distinguish between alerts that represent fail conditions and those that do not.

Removing a load from an aborted cycle can present a risk of worker exposure to residual sterilant. The manufacturer's written IFU should be followed, safety precautions should be observed, and personnel should wear PPE. Items from aborted cycles should be removed from packaging, cleaned if needed to remove residual chemicals, repackaged, and processed according to manufacturer's written IFU.

Rationale: When a sterilizer malfunctions, the load is considered unsterile. Simply altering the cycle parameters of a malfunctioning sterilizer will not correct a problem. The sterility of future loads will be jeopardized if the sterilizer continues to be used without repair and requalification to verify that the sterilizer performs to specifications after the correction of a malfunction. To restore a sterilizer to full performance, it is necessary to identify the exact cause of the malfunction.

A major repair is a repair outside of normal maintenance, such as rebuilding or upgrading controls. When repairs involve parts that are usually replaced under preventive maintenance procedures, the sterilizer can be returned to service after verification of the sterilizer's operation to the manufacturer's specifications.

Sterilizer software controls are designed to detect inadequate cycle conditions and will often abort the cycle when the required parameters for the process have not been met. Some sterilizers will also provide various types of alerts regarding equipment performance.

13.8 Chemical indicators

13.8.1 General considerations

Chemical indicators are sterilization process monitoring devices that are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; CIs should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. All CIs should be used according to the CI manufacturer’s written IFU.

13.8.2 Using chemical indicators

Health care personnel should use the CI cleared by the FDA for use with a specific sterilization system. The CI manufacturer should be consulted for information on the reliability, safety, and performance characteristics of the product. The CI manufacturer’s written IFU should be consulted to explain the frequency of CI use, the placement of CIs, the interpretation of CI results, the reliability of the CI in maintaining end-point response during storage of sterilized items, the sterilization conditions that the CI will detect, the shelf life of the CI, and the storage requirements for the CI before and after sterilization.

NOTE The IFU for the CI provides information about the sterilization methods and systems with which it can be used.

An external CI should be used on the outside of each package unless the internal indicator is visible. The external CI should be examined after sterilization and also before use of the item to verify that the item has been exposed to the sterilization process.

An internal CI should be used inside each package, tray, pouch, or containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) to be sterilized. The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration. The CI should be retrieved at the time of use and interpreted by the user.

The user shall receive education and training and demonstrate competency about the performance characteristics of the CI and the interpretation of the results.

For general information about CIs, see ANSI/AAMI/ISO 11140-1 [2] and ANSI/AAMI/ISO 15882 [6].

Rationale: Examining the CI after sterilization and before use enables the user to verify that the item has been exposed to the sterilization process.

13.8.3 Nonresponsive or inconclusive chemical indicators

If the interpretation of the CI suggests inadequate processing, the contents of the package should not be used. The interpreter should inform the designated supervisor, who should return the complete unused package, including load identification and the CI, for follow-up. The supervisor or delegated individual in the sterilizing area should then decide whether to recall that sterilized load. This decision should be based on the results of physical monitoring; the results of CIs elsewhere in the load; and, if applicable, the results of BI monitoring. If BI monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and should not be used until the BI results are obtained.

Rationale: If a CI is nonresponsive or inconclusive, it is possible that the entire load is nonsterile (i.e., the sterilization process failed). It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load. Therefore, a single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile.

13.9 Biological indicators

13.9.1 General considerations

Biological indicators are sterilization process monitoring devices consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions.

Process challenge devices are challenge test packs containing a BI or a BI and a CI. A PCD is used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed.

All BIs and PCDs should be used in accordance with the manufacturer's written IFU.

Rationale: Biological indicators are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements. To provide useful information about the lethality of the sterilization process, the appropriate BI must be chosen for the sterilization cycle and used correctly (in accordance with the manufacturer's written IFU). Manufacturers of BIs are required to provide written instructions on the storage, handling, use, and microbiological testing of their products. Biological indicators consist of spores in or on a carrier and provide a direct measure of lethality of a cycle. Self-contained BIs (SCBIs) include incubation media with the spore carrier in a single vial. Biological indicators are incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (i.e., survived the sterilization process) or fail to grow (i.e., were killed by the sterilization process). Biological indicators are intended to demonstrate whether the conditions were adequate to kill a large number of highly resistant bacterial spores.

13.9.2 Using biological indicators and process challenge devices

Processing personnel should use the BIs and PCDs cleared by the FDA for use with that system, or BIs and PCDs cleared by the FDA as substantially equivalent. Consult the manufacturer's written IFU on the storage, handling, use, and microbiological testing of their products.

NOTE BIs and commercially available PCDs used in health care facilities are medical devices that require FDA premarket clearance. The IFU for the BI or PCD provides information about the sterilization methods and systems with which it can be used.

Processing personnel should receive education, training, and complete competency verification activities regarding the performance characteristics of the BI and PCD and the interpretation of the results.

For general information about BIs, see ANSI/AAMI/ISO 11138-1 [1] and ANSI/AAMI/ISO 14161 [5]. For general information on PCDs, see AAMI TIR31 [22].

Process challenge devices containing BIs should be used for sterilizer qualification testing after installation before initial use of the sterilizer; after relocation, major repairs, or malfunctions of the sterilizer; and after sterilization process failures. A PCD with a BI should also be used daily, but preferably in every sterilization cycle or per the sterilizer manufacturer's recommendations.

Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a sterilization cycle could vary from one cycle to another. The less frequently the sterilizer is used, the greater the opportunity for the occurrence of an unnoticed event that could affect the safety or sterility of the device.

13.10 Sterilizer testing

13.10.1 General considerations

All gaseous and vapor chemical sterilizers should be tested using BI PCDs daily or preferably every load, and upon installation, relocation, sterilizer malfunctions, major repairs, and sterilization process failures. Sterilizer testing after installation, relocation, and major repairs should be conducted in the health care facility by processing personnel in cooperation with the manufacturer. The testing should be performed between the time the sterilizer is installed,

relocated, or repaired and the time it is released for use or returned to service in the health care facility. Processing personnel should follow the manufacturer's written IFU, which should include the BI and PCD to use, the placement of the BI PCD in the load or chamber, whether the chamber should be full or empty, and the number of cycles to run.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores and the PCD is used to provide a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed in the sterilization cycle. The purpose of testing a sterilizer after installation or relocation is to assess sterilizer performance in the environment in which it will be used. Satisfactory test runs verify that the sterilizer is in good working condition after shipment from the manufacturer or relocation from its previous site and that it will function effectively. Sterilizer testing after major repairs is intended to ensure that the sterilizer performs to specifications after the correction of a malfunction or a sterilization process failure.

13.10.2 Qualification test procedure and acceptance criteria

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD should be labeled with sterilizer lot and load information.

b) The PCD should be positioned in the load or chamber according to the sterilizer and PCD manufacturers' written IFU, and a normal cycle should be run.

c) Upon completion of the sterilization cycle, the manufacturer’s written IFU for removing the PCD from the load or chamber and the BI from the PCD should be followed. During the removal and transfer process, processing personnel should be careful to avoid contamination of the BI or injury to themselves. The BI should be identified and then incubated according to the written IFU of the BI manufacturer.

d) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the incubation temperature. Test and lot control numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the control and test BIs should be repeated.

NOTE If several test BIs from the same lot are run on the same day and in the same incubator, only one control BI from that lot need be used.

All monitoring results, including results from BI controls, should be interpreted by a qualified individual, and should be included in the sterilizer records.

Rationale: Negative results from the test BIs or spore test strips, positive results from control BIs, and cycle printout records demonstrating correct and complete sterilization cycles provide verification that the sterilizer has been installed or repaired and that it will function effectively in the facility in which it is installed.

13.10.3 Routine test procedure

The test procedure is as follows:

a) Before being exposed to the sterilization cycle, the PCD should be labeled with sterilizer and lot information.

b) The PCD should be positioned in the load according to the sterilizer and PCD manufacturers' written IFU, and the cycle should be run.

c) EO sterilizers should be tested using BI PCDs in every load. All other gaseous or vaporized chemical sterilizers should be tested using BI PCDs daily when the sterilizer is in use, but preferably in every sterilization cycle.

d) Upon completion of the sterilization cycle, the PCD should be removed from the load and the BI removed from the PCD according to the manufacturer's written IFU. During the removal and transfer process, processing personnel should be careful to avoid contamination of the BI or injury to themselves. The BI should be identified and then incubated according to the written IFU of the BI manufacturer.

e) Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the incubation temperature. Test and lot control numbers should be recorded. Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the control and test BIs should be repeated.

NOTE If several test BIs from the same lot are run on the same day, only one control BI from that lot need be used.

13.10.4 Routine test acceptance criteria

An acceptable process is evidenced by negative results from all test BIs in the PCD, positive results from control BIs, and readings from physical monitors and CIs showing that the sterilization cycle was correct and complete. All monitoring results, including results from BI controls, should be interpreted by a qualified individual, and should be included in the sterilizer records.

13.10.5 Positive BI results

The following actions should be taken if a BI test is positive:

a) Positive BI results (other than those from viability/positive controls) should be verbally reported immediately to the sterile processing supervisor or other designated personnel and to infection prevention and control personnel. This notification should be followed by a written report. The report and notification should include:

   1) the time and date of the questionable sterilizer cycle;

   2) a description of the sterilizer and load, including the lot control number, product and patient name, and other identifying information;

   3) the results of physical monitoring and of CIs, if applicable, as obtained from the user; and

   4) any other information that could be useful in determining whether the report is valid or is questionable because of human error.

b) Because a sterilization failure has occurred, items processed in that sterilizer since the sterilization cycle having the last negative BI should be considered unsterile. They should be retrieved, if possible, and reprocessed. The sterilizer in question should be taken out of service.

c) A presumptive identification of the microorganisms present on the "failed" (positive) BI should be performed in accordance with the BI manufacturer's written IFU, and, if applicable, the BI transfer technique should be reviewed. The load recall should *not* be delayed while this testing is being performed. The recalled items can be quarantined until the presumptive test results are known.

d) Microbiology, sterile processing, and facility maintenance personnel should attempt to determine the cause of the positive BI and sterilization process failure and arrange for corrective action.

e) After the cause of the sterilization process failure has been determined and corrected, if required by the investigation, the sterilizer in question should be immediately rechallenged with BI PCDs. Until the results of retesting are satisfactory, the performance of the sterilizer should be considered in question.

Rationale: Conducting the recommended protocol when positive BI results occur will provide valuable data in support of corrective actions and aid in identifying potential improvements in work practices.

13.10.6 Positive BI microbiological verification testing

For positive BIs, a presumptive identification should be performed according to the BI manufacturer's written IFU to determine whether the recovered microorganism is the test microorganism from the BI or an accidental contaminant.

Rationale: Presumptive identification distinguishes accidental contamination of the BI after removal from the PCD from a true positive BI that resulted from sterilization failure. In the latter case, there would be incomplete destruction of the test microorganisms on the BI.

13.11 Product release

Product release should be an active decision based on evaluation of all available data from the sterilization or high-level disinfection process for the particular load. Loads that do not meet the criteria for release should be clearly identified so that they are not mistakenly distributed.

Rationale: Releasing processed devices based on all quality control measures is critical in providing safe and effective products for the care and treatment of patients.

13.12 Product recalls

13.12.1 General considerations

Written policies and procedures for the recall of issued or stored packaged items that have been processed with LCSs/HLDs or terminal sterilization should be developed in cooperation with the infection prevention and control committee and the risk management committee of the health care facility. Written policies and procedures for the identification of items not packaged or stored but immediately used should also be developed. Policies and procedures should be documented, and records should be maintained. The supervisor or designated individual should decide on the basis of the health care facility's policies and procedures, the manufacturer's written IFU, the circumstances surrounding the event, or other relevant information, whether a recall of processed supplies should be implemented. Whenever there is evidence of a sterilization or LCS/HLD process failure, the infection preventionist and other involved personnel (e.g., the director of the area where the suspect items were used) should be notified so that follow-up surveillance of patients can be conducted. Written policies and procedures should be developed for compliance with the Safe Medical Devices Act of 1990 as it pertains to failures of reusable medical devices (i.e., FDA's Medical Device Reporting [MDR] regulations of 21 CFR 803). For additional information on user facility MDR requirements, see FDA (1996) [338].

Rationale: Establishing recall procedures can help ensure patient safety, compliance with the user facility reporting requirements of the FDA's MDR regulations, facilitate the identification and retrieval of items suspected to be unsterile or incorrectly high-level disinfected, and provide for adequate follow-up actions (e.g., quarantine of the sterilizer or automated processing equipment, notification of physicians and affected areas, surveillance of patients).

13.12.2 Recall procedure

A recall procedure should:

a) be written;

b) outline the circumstances for issuing a recall order;

c) designate the person or people authorized to issue a recall order; and

d) designate the personnel responsible for reporting on the execution of a recall order.

13.12.3 Recall order

A recall order should:

a) include all items processed back to the last negative BI (if applicable) or the last passing MRC indicator (if applicable);

b) be immediately communicated to affected areas and followed by a written order;

c) identify products to be recalled by lot number (if applicable), product or patient name, or other information;

d) identify the people or areas to whom the order is addressed;

e) require the recording, in terms of kind and quantity, of the products obtained in the recall; and

f) specify the action to be taken by the people receiving the order (e.g., destruction or return of product).

13.12.4 Recall summary report

A summary report of a recall order should:

a) identify the circumstances that prompted the recall order;

b) specify the corrective actions taken to prevent a recurrence;

c) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and

d) provide verification that the recalled items were processed or destroyed.

13.13 Outbreak report

The people responsible for the health care facility's infection prevention and control program and risk management function should report any outbreaks associated with chemical sterilization or high-level disinfection processes to the local or state department of health, which will complete the investigation and report to the CDC. The health care facility should report the results of the investigation to the FDA, the medical device manufacturer, the processing equipment manufacturer, and the manufacturer of the LCS, HLD, and/or chemical processing/sterilization system (ASGE, 2003 [77]).

13.14 Quality process improvement

13.14.1 General considerations

This section identifies performance measures and process monitors that can be used for continuous quality improvement (CQI) programs. CQI programs are recognized as an effective means of improving the performance of any process. For chemical sterilization and high-level disinfection, a CQI program encompasses the entire process: decontamination, preparation, packaging (if applicable), chemical sterilization or high-level disinfection, quality control, storage (if applicable), and product distribution.

Procedures for cleaning, high-level disinfection, and chemical sterilization, and terminal sterilization should be based on the manufacturers' written IFU (endoscope, cleaning solution, LCS/HLD, AER, and/or sterilizer, as applicable) as part of a documented quality process that measures objective performance criteria. (See Annex D.) This quality process should be developed in conjunction with designated personnel and integrated into the overall quality process in the health care facility. Variables in the system can be controlled to achieve assurance of product quality and process efficacy. Monitoring frequency will vary, depending on the quality improvement goals, health care facility policies and procedures for the handling of unfavorable or unplanned events, and type of process variable.

A root cause analysis should be completed for any problem relating to any aspect of cleaning, high-level disinfection, or chemical sterilization processing that could pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected.

There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Quality processes can be enhanced by audits that are conducted on a regular basis. The information from these activities should be summarized and made available to designated individuals or groups (see ANSI/AAMI ST90 [18]).

Rationale: Measurements of process performance allow cleaning, high-level disinfection, and chemical sterilization processes to be monitored against a predetermined level of quality. Evaluation of findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data essential to assessing the effectiveness of the processes and making improvements in performance.

13.14.2 Risk analysis

Risk analysis = risk assessment + risk management + risk communication
Disinfection is not sterilization, but a high-level disinfected device is one that should be free of viable pathogens, excepting spores such as those of *Clostridioides difficile (C. diff).* The Spaulding Classification of the device will define the level of disinfection or sterilization required. Devices that require at a minimum high-level disinfection with a chemical disinfectant are usually classified as semi-critical devices, as they are in contact with mucous membranes or non-intact skin. As with sterilization, it is recognized that the effectiveness of these processes cannot be fully verified by subsequent inspection and testing of the product. For this reason, high-level disinfection processes are validated for use and the performance of the process is monitored routinely, including any associated equipment. This is also the case for sterilization processes.

A quality system for processing medical devices in health care facilities is based on a validated system, including manual or automated steps in the process (see ANSI/AAMI ST90 [18]). For automated equipment, validation will involve the AER or sterilization process manufacturer and designated representatives of the health care facility, who will conduct installation qualification and operational qualification testing. The individual device manufacturer and the AER manufacturer recommend validated means of cleaning and/or disinfecting or sterilizing the specific devices to be processed, in lieu of a formal performance qualification.

NOTE The "validated cycle" provided by the medical device manufacturer is often based on the assumption that the device is to be processed alone.

In health care facilities, a processing risk analysis, in its broadest sense, includes risk assessment, risk management, and risk communication:

a) **Risk assessment** involves identifying the source of a failure, estimating the likelihood that such a failure will occur, assessing the consequences if that failure does occur, and assessing how prepared the facility is to manage the failure. It should be assumed that at some time a failure will occur.

b) **Risk management** entails determining which of the failures identified in the risk assessment process require management and selecting and implementing the plans or actions that are needed to ensure that those high-level disinfection failures are controlled.

c) **Risk communication** involves an interactive dialogue between sterile processing personnel, operating room personnel, endoscopy personnel, infection preventionists, and risk management professionals that actively informs the other concerned parties, including patients. This process is the facility's recall procedure.

The processing risk analysis should be part of the health care facility's overall infection prevention and risk control analysis in accordance with accreditation agency requirements. It should be performed at least annually and should be reevaluated whenever significant changes occur.

13.14.3 Point of use

Procedures for decontamination, which begins at point of use, should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in collaboration with designated personnel and should be integrated into the overall quality process in the health care facility. Written policies and procedures should consider CDC recommendations, national voluntary standards and recommended practices, and the recommendations of the flexible endoscope manufacturer. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors, including tests for monitoring and verifying the parameters of the point of use

treatment. Monitoring frequency will vary, depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

A root cause analysis should be completed when a patient safety event occurs (not primarily related to the natural course of the patient's illness or underlying condition) results in death, permanent harm, or severe temporary harm (Joint Commission, 2015 [188]).

Rationale: Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data that can be used to assess the effectiveness of the process and make ongoing improvements in performance.

13.14.4 Decontamination

Procedures for decontamination should be based on a documented quality process that measures objective performance criteria. This quality process should be developed in collaboration with designated personnel and should be integrated into the overall quality process in the health care facility. Written policies and procedures should consider federal, state, and local regulations; CDC recommendations; national voluntary standards and recommended practices; and the recommendations of medical device and processing equipment manufacturers. Variables in the system should be controlled to achieve assurance of quality and process efficacy. Performance measures should be developed to monitor environmental, performance, and process factors, including tests for monitoring and verifying the parameters of the cleaning process. Monitoring frequency will vary, depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

A root cause analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The root cause analysis should define and resolve the problem, and the system should be monitored to ensure that the problem has been corrected. There should be a planned, systematic, and ongoing process for verifying compliance with procedures. Auditing results should be routinely summarized and submitted to the infection prevention and control personnel for review.

Rationale: Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data that can be used to assess the effectiveness of the process and make ongoing improvements in performance.

13.14.5 Liquid chemical sterilization, high-level disinfection, and gaseous and vaporized chemical sterilization

Procedures for liquid chemical sterilization, high-level disinfection, and gaseous and vapor chemical sterilization should be based on a documented quality process that measures objective performance criteria. The quality process should be developed in conjunction with designated personnel and integrated into the overall quality process in the health care facility. Monitoring frequency will vary depending on the quality improvement goals, on the health care facility's policy and procedures for the handling of untoward events, and on the type of performance measure.

a) **Use of LCSs/HLDs.** Performance measures should include, but are not limited to, the following:

   — verification of training and continuing education;

   — correct choice of and use of LCSs/HLDs and PPE;

   — correct loading of items into the solution container or automated processing equipment;

   — selection of LCS/HLD cycle parameters;

   — selection and use of CIs, spore test strips, and solution test strips or chemical monitoring devices;

   — accurate load records;

— documentation of physical and chemical monitoring; and

— adherence to device, LCS/HLD, and automated processing equipment manufacturers' written IFU.

b) **Gaseous and vapor chemical sterilization processes.** Performance measures should include, but are not limited to, the following:

— verification of training and continuing education;

— correct loading of items into the sterilizer chamber;

— selection of chemical sterilization cycle parameters;

— selection and use of CIs and BIs;

— accurate load records;

— documentation of physical, chemical, and biological monitoring; and

— adherence to device and sterilizer manufacturers' written IFU.

c) **Handling and transfer.** Performance measures should include, but are not limited to, the following:

— selection and use of attire;

— correct techniques for unloading the sterilizer, automated processing equipment, or solution container; and

— correct techniques for transferring items to the point of use.

A root cause analysis should be completed when a patient safety event occurs (not primarily related to the natural course of the patient's illness or underlying condition) results in death, permanent harm, or severe temporary harm (Joint Commission, 2015 [188]).

Rationale: Controlling variables in the system can help to ensure quality and process efficacy. Ensuring that high-level disinfection or liquid or gaseous and vapor chemical sterilization has been achieved will minimize the potential risk to patients. Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality. Analysis of this information provides a method of identifying problems or shifts in activities and making improvements in the system.

13.14.6 Functional areas for product and process improvement

13.14.6.1 Workplace design

Optimization of product and process performance relies on efficient workplace design. Problems such as cross-contamination, excessive processing costs, product failures, inefficient time usage, and so on can be created or exacerbated by poor workplace design. Workplace design encompasses the following:

a) the physical layout of the processing area;

b) the functional workflow patterns;

c) the physical facilities (e.g., the mechanical and electrical systems, lighting, plumbing, ventilation, environmental controls); and

d) the types and locations of processing equipment and supplies.

13.14.6.2 Processing policies and procedures

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process. The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process. Written procedures should be reviewed, and current practices should be audited for compliance in the areas included in the CQI program. Examples of CQI program areas include the following:

a) training, continuing education, and competency verification;

b) product identification and traceability (i.e., lot control numbers and load records);

c) monitoring cleaning effectiveness;

d) monitoring manual processes that use LCSs/HLDs;

e) monitoring automated processes that use LCSs/HLDs;

f) monitoring gaseous and vapor chemical sterilization processes;

g) product testing;

h) product recalls; and

i) workplace safety training (including safe use of chemicals and safe handling of biohazards).

13.14.6.3 Product use

Evaluating the performance of products that have been or will be used can offer important feedback on the effectiveness of the process and the products selected. Performance measures can come from internal evaluations, end-user feedback, supplier testing, and repair records:

a) **Internal evaluations.** Internal evaluations can be used to audit the quality of finished products. For example, instruments can be checked for functionality, packaging, and delivery. Preprocessing decontamination can be evaluated by visually examining instruments for contamination. Product recalls can be evaluated by reviewing records of actions following documented chemical sterilization or high-level disinfection process failures. Periodic product monitoring can be evaluated on the basis of the loads or cycles tested and the actions taken as a result of failures.

b) **End-user feedback.** A formal documented system to log, investigate, and resolve complaints and product failures should be established. Issues such as patient infections, PPE failures, and malfunctioning endoscopes should be documented, monitored, and tracked over time. A procedure should be established for investigation and remediation of serious and repeat problems.

c) **Supplier testing.** The manufacturer should thoroughly analyze concerns relative to the performance of products or supplies through testing or other means. Processing personnel should make a written request to and receive a response from any vendor whose products, supplies, or services are in question. All correspondence should be filed with the corresponding complaint, including details of the investigation, the findings, and any actions taken by the vendor to resolve the problem.

d) **Repair records.** Review of instrument repair records might show a pattern. Once identified, the cause for the repair can be reviewed, corrected, and then monitored to ensure that the problem has been resolved.

13.14.6.4 Implementation of product and process improvements

There is no single right way to implement a CQI program. The program should be customized to the individual facility. However, a team approach has been proven to be successful because it allows direct input from multiple employees and results in a superior program.

Employees who are actively involved in and responsible for the day-to-day functions outlined in the plan should be members of the team. This approach should generate input from those most knowledgeable in methods of effectively improving the program. Additionally, such involvement may promote a sense of ownership that may lead to a higher degree of commitment on the part of those endoscope processing team members implementing the program.

The single most important issue for those charged with implementing a CQI program is the accurate collection of data using the facility plan for documenting process monitoring and product performance (developed as part of the CQI program). The frequency and type of information generated will vary depending on the level of control established in the documentation plan. Facilities with processes that are uncontrolled or highly variable will require increased process monitoring and documentation, which can be reduced over time as the program brings these processes under improved control.

Occupational safety is symbiotic with patient safety and is a key part of the quality system. Occupational safety records that should be kept as part of the quality system include

a) maintenance records such as exhaust air flow checks;

b) exposure records from gas monitors;

c) employee safety training (chemicals used on-site, OSHA Hazard Communication Standard, emergency procedures, work instructions for safe use of equipment); and

d) medical evaluation of personnel using respirators.

The CQI program should assess all components of chemical sterilization and high-level disinfection processes for the ongoing ability to achieve the desired outcome of consistently delivering an efficacious product to the user. Performance improvement plans, when needed, should be implemented to enhance chemical sterilization and high-level disinfection processes on the basis of this assessment. Examples of measures to be considered when assessing chemical sterilization and high-level disinfection processes include trending data over a defined time period related to

a) the number of items processed;

b) the number of failed cleaning verification tests, if applicable;

c) the number of BI tests, if applicable;

d) the number of BI failures for each chemical sterilization process, if applicable;

e) the number of physical parameter failures;

f) the number of failed CIs, if applicable;

g) the number of spore test strips, if applicable;

h) the number of spore test strip failures, if applicable;

i) the number of solution test strip or chemical monitoring device failures for processes that use LCSs/HLDs;

j) competency verification (the percentage of endoscope processing team members successfully completing education, training, and competency verification activities);

k) timing and completeness of preventive maintenance of gaseous and vapor chemical sterilizers and automated processing equipment;

l) ability to locate all items during recalls;

m) completeness of test records;

n) results of microbial surveillance culturing, if applicable; and

o) occupational safety records.

For more information about implementing a quality management system approach, see ANSI/AAMI ST90 [18].

14 Device repair and loaned endoscopes

14.1 General considerations

Flexible and semi-rigid endoscopes and accessories shall be carefully inspected to identify defects or malfunctions during each step of processing and prior to patient use. Defects and malfunctions identified during use shall be clearly described as to the location and nature of the defect or malfunction and reported according to facility procedure. Routine preventive maintenance should be addressed in each facility policy and procedure. Processing staff should be aware of endoscope preventive maintenance and repair strategies.

Transport or shipping is done following decontamination and disinfection or sterilization procedures, including drying, for damaged endoscopes. A device to be shipped for repair should be placed in a securely sealed, leak-proof primary container. If the endoscope is considered contaminated, the package must be clearly identified as contaminated material and must be packaged, labeled, and shipped in accordance with the manufacturer's written IFU, the requirements of the carrier (U.S. Postal Service or private carrier), and the applicable U.S. Department of Transportation (DOT) regulations (49 CFR 170–178). Endoscopes that are processed are packaged, labeled, and shipped in accordance with the manufacturer's written IFU, the requirements of the carrier (U.S. Postal Service or private carrier), and with the applicable U.S. DOT regulations (49 CFR 170–178). The shipper is responsible for correct packaging and labeling.

A facility-specific policy and procedure shall be in place with details on communication and method when a defect or malfunction is detected at the point of use. The policy and procedure should specify the:

a) responsibility and accountability for defect and/or malfunction documentation;

b) processing procedures for repair handling;

c) records to be kept, including repair information;

d) review of repair records to determine trends; and

e) review of repair records to identity endoscopes and/or accessories requiring replacement or follow-up.

Regulatory reporting can be required.

14.2 Point of use detection and communication

At the point of use, an endoscope and/or accessories in need of repair should be clearly identified before processing and removed from service until processed, repaired, and processed before reuse. For removal from service and transport, the endoscope and/or accessories should be placed in a containment device to prevent additional damage.

For a device identified as defective or malfunctioning at the point of use, a tag should be affixed and include the following information:

a) flexible or semi-rigid endoscope serial number or unique identifier;

b) date of occurrence;

c) time of occurrence;

d) department or procedure room where procedure was performed (e.g., Procedure Room 3);

e) endoscopist;

f) a clear description of the malfunction or defect (e.g., “foggy” view, unable to articulate distal end, irrigation not flowing, suction not working, unable to pass biopsy forceps through channel); and

g) name of individual completing the report.

14.3 Processing area detection and communication

Flexible and semi-rigid endoscope and/or accessories identified for repair should be placed in a designated location to be processed, following the manufacturer’s written IFU for damaged endoscope processing, before additional examination, repair, or shipping to another facility for repair.

Following processing, the damaged endoscope and/or accessories should be delivered to the designated location for repair.

Additional information should be added to the defect/malfunction tag initiated at the point of use:

a) failed or passed leak test, for endoscope to be repaired;

b) condition of all channels (e.g., cleaning brush passed easily, channel easily flushed);

c) condition of accessories (e.g., suction valve cannot be inserted);

d) condition of external surface (e.g., head of endoscope scratched in area of biopsy port);

e) date of processing;

f) time of processing;

g) process used to achieve high-level disinfection or sterilization;

h) name of individual completing the processing; and

i) name of individual completing the report.

14.4 Health care facility point of repair transfer

The facility’s designated process should be in place to notify the repair person or vendor.

Documentation should include the tracking number or identification of the individual picking up the items for repair, the date, and the time.

14.5 Return to health care facility from repair

Documentation from the repair service should include the following:

a) method, date, and time of return;

b) decontamination procedure performed by repair facility;

c) type of service performed;

d) parts replaced; and

e) recommendations for future prevention of damage.

Upon return from repair, the endoscope and/or accessories should be carefully inspected by the receiving facility for defects or malfunction prior to return to service.

The endoscope and/or accessories returned from repair shall be fully processed in accordance with the health care facility processing policy before patient use.

14.6 Loaned endoscopes

14.6.1 Policy and procedure

There should be a facility policy and procedure for lending or borrowing flexible or semi-rigid endoscopes**.** The policy should be developed in conjunction with infection prevention and control, risk management, materials management, perioperative services, GI/endoscopy, clinical engineering, and other personnel as deemed necessary. Personnel should be knowledgeable in the facility's policies and agreements for loaned endoscopes. A request for a loaned endoscope to be used during the repair period should be made only after facility policies established to maintain records, including patient traceability, are considered. The policy and procedure should address the following:

a) Upon receipt, inspect the loaned endoscope for damage and consistency with the original endoscope.

   1) Ensure that the manufacturer's written IFU have been provided for the specific loaned endoscope.

   2) If any differences are noted in the loaned endoscope compared to the endoscope it replaces (e.g., it has an additional channel), in-service all staff members, with competencies verified, in processing the endoscope.

   3) Confirm that correlating processing accessories and connection adapters are available for effective processing.

   4) If any damage is noted in the loaned endoscope, contact the facility or company that loaned the endoscope to report the damage and request a replacement.

   5) Document the loaned endoscope by manufacturer, model, date received and serial number.

b) Completely process the loaned endoscope, according to the manufacturer's written IFU, before use.

c) Prior to return, completely process the loaned endoscope.

d) Inspect the loaned endoscope for damage. Document the condition of the endoscope and date of return.

For more information on management of loaned instruments, see AAMI TIR63 [24].

14.7 Use of loaned endoscopes during microbial surveillance

It might be necessary for health care facilities performing microbial surveillance to use loaned endoscopes while awaiting culture results from quarantined endoscopes. The same policy and procedures outlined in 14.6.1 apply.

14.8 Quality measures for repairs

Repeated failed cleanliness testing and/or persistent positive microbial culture surveillance results could be an indication of a damaged endoscope. The device should be removed from service and examined by a trained repair technician.

Failed functional testing (e.g., failed leak testing, angulation issue) is an indication of a damaged endoscope. The device should be removed from service and examined by a trained repair technician.

Repair history documentation should be reviewed on a periodic basis to identify trending by the following:

a) model of endoscope;

b) individual endoscope (serial number or unique identifier);

c) type of repair;

d) processing method;

e) individual(s) performing processing;

f) individual performing clinical procedure; and

g) procedure type in which the endoscope was used.

A preventive maintenance program should be in place to plan thorough inspection of all channels and working mechanisms of endoscopes and accessories for function or defects.

Infection prevention and control, processing, clinical engineering, and procedure area personnel should be part of the quality review team to:

a) review repair documentation;

b) maintain a perpetual physical inventory of semi-rigid and flexible endoscopes;

c) review competency testing results; and

d) make recommendations based on trending.

15 New product evaluation

15.1 General rationale

Periodically, new products enter the market for which AAMI does not offer guidance for application. Some products do not fall within AAMI's purview. For those that do, AAMI applies a rigorous consensus review process that includes committee discussion, balloting, public review, and subsequent publication; this consensus review process can be quite lengthy. When any product is being considered for use within a facility, it is the responsibility of the intended users to evaluate the product using a systematic process of product evaluation and to establish policies and procedures that reflect this process and that are appropriate to the health care organization. This is especially true when the health care organization is considering a product for which there are no guidelines from AAMI or other similar professional organizations.

15.2 Considerations

The following are considerations associated with conducting a product evaluation:

a) Establish a multidisciplinary committee with representation from those who will be affected by the new product. For example, for a product related to steam, low-temperature, or chemical sterilization, representation could include, but not necessarily be limited to, infection prevention and control, operating room, sterile processing, endoscopy, risk management, and staff development/education personnel.

b) Collect and distribute to the multidisciplinary committee information related to the product. Such data should include, but not necessarily be limited to, the following:

   — FDA clearance documentation, if applicable;

   — relevant research articles published in peer-reviewed journals;

   — literature and written IFU from the device, equipment and/or chemical manufacturer;

   — experts' opinions; and

   — reports from peers who are using or have trialed the product.

c) In addition to evaluating the product's intended application, consider the following:

   — ease of understanding the manufacturer's written IFU;

   — contribution to patient and employee safety;

- any legal implications associated with use of the product;
- cost/value analysis (return on investment);
- personnel education necessary to implement use;
- ease of use of the product;
- related safety issues;
- compatibility of the product with existing equipment and products;
- environmental impact;
- availability of ongoing support from the vendor for such services as maintenance; and
- impact on standardization of product inventory.

d) If a product trial is indicated, consider the following guidelines:

- establish a time limit for the trial;
- identify the personnel and departments that should trial the product;
- establish the amount of product that should be evaluated;
- evaluate the manufacturer's written IFU;
- develop evaluation tools through the multidisciplinary committee identified above;
- determine and implement the education and demonstrations needed for the trial;
- define the desired outcome; and
- analyze the data and compare the actual outcome with the desired outcome.

For more comprehensive information on the evaluation of new products, see AORN (2018f) [41].

Annex A
(informative)

Alternatives for keeping cool in the processing environment

A.1 Introduction

The healthy human body maintains a core temperature of about 98.6 °F (37 °C). Core body temperature will stay basically the same no matter what the temperature of the surrounding area might be or what the activity level of the person might be. A healthy safe core temperature is between 98 °F and 100 °F for most people. Some individuals might naturally have a core temperature that is slightly lower or higher than 98.6 °F. If a person is exposed to an environment that is very warm or very cool, the body will take steps to bring the core temperature back to the healthy range. The process of regulating core temperature is called thermoregulation.

The hypothalamus controls thermoregulation. When core temperature becomes too high or too low, the hypothalamus issues instructions to muscles, organs, glands, and the nervous system. If the body needs to cool down, the instructions will cause sweating and vasodilation to occur. As sweat evaporates, it will cool the skin, which will help lower core temperature. The central nervous system can cause the capillaries under the skin to open or dilate, which increases blood flow to the skin surface and allows the body to release heat.

There are steps that can be taken to heat or cool the body as needed. In winter, people wear additional layers of clothing, and in summer people wear lighter-weight clothing. In addition, eating cool foods like ice cream or iced drinks and cooling the pulse points of the body can help to cool the body. The opposite is also true. Eating warm foods and warming the body's pulse points will help to warm the body.

The American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) has a standard on thermal comfort, ANSI/ASHRAE 55-2013, *Thermal environmental conditions for human occupancy* [33]. This standard provides information on working in various environmental conditions and what most people would consider to be comfortable. The University of California Berkeley Center for the Built Environment has developed a tool to assist companies in determining whether the environment in a particular room meets this standard. This tool can be found at no cost on the Internet. The tool measures thermal comfort based on sustained activity for one hour. Functionality to evaluate comparisons of different variables is available. Several variables can be addressed in the tool. Detailed help information on how to use the thermal comfort tool is available through a help link on the tool's website. Information on determining the metabolic rate to be used can be found in ISO 8996, *Ergonomics of the thermal environment—Determination of metabolic rate* [48]. Information regarding the impact of clothing can be found at ISO 9920, *Ergonomics of the thermal environment—Estimation of thermal insulation and water vapour resistance of a clothing ensemble* [49].

It is possible that the protective attire worn in the decontamination area could cause workers to feel overheated and to perspire. Lowering the ambient temperature might not be an efficient mechanism for reducing body temperature. This Annex discusses alternatives for how personnel can keep cool in the sterile processing environment.

A.2 Decontamination environment

The temperature and relative humidity of the decontamination area/room of the sterile processing department is controlled to minimize potential growth of bacteria, fungi, and molds and to provide a comfortable working environment. The personal protective equipment (PPE) required to be worn when working in the decontamination area/room can be uncomfortable even when the temperature of the decontamination area is within the recommended range. Some individuals might feel overheated when working in this area and wearing PPE. Lowering the room temperature is not effective in lowering the body temperature of individuals wearing PPE because not enough skin is exposed to the air for perspiration to evaporate and cool the body. More effective alternative measures can be taken to make workers comfortable.

A.3 Protective attire

Protective attire worn in the decontamination area might be uncomfortable because it does not allow the body to disperse heat that is generated while working. Many of the protective gowns and aprons used in the decontamination area are made of plastic or other fluid-resistant materials. The plastic or other fluid-resistant material provides an excellent barrier to bloodborne pathogens, but it does not allow for the body to disperse any excess heat that might build up. This heat can cause employees to sweat, which can be uncomfortable.

A.4 Alternative cooling methods for personnel working in the decontamination area/room

Rather than being exposed to heat for extended periods of time during the course of the job, workers should, wherever possible, be permitted to distribute the workload evenly over the day and incorporate work/rest cycles. Work/rest cycles give the body an opportunity to get rid of excess heat, slow down the production of internal body heat, slow down the heart rate, and provide greater blood flow to the skin. In the evaluation of an appropriate work/rest schedule, shorter work periods and more frequent rest periods should be considered:

a) as temperature rises;

b) as humidity increases;

c) when there is no air movement;

d) when protective clothing or gear is worn; and

e) for heavier work.

In general, more frequent, shorter periods of exposure to heat are better than fewer longer exposures. Individual requirements can vary greatly (OSHA, 2019 [225]).

It is important that a person is well hydrated before donning PPE. Hydration will help to keep the body cool. Employees can take breaks to maintain hydration.

Cooling devices worn under PPE could provide additional comfort. Cooling devices can be reusable or single-use and include:

a) cooling bandanas, skull caps, or head bands;

b) cooling neck scarfs or towels; and

c) cooling vests.

Frequent breaks might also be needed so that cooling devices or cool water can be applied to body pulse points. Pulse points include the back of the neck, the inside of the wrists, the inside of the elbows, the back of the knees, the inside groin area, and the head, between the temple and ear. Applying cool water or ice to these areas can help to cool the body.

Because no two facilities or individuals are the same, it is important to establish policies and procedures to provide for the comfort and safety of the personnel working in the SPD decontamination area/room environment.

a) The plan should address the preferences of the individual worker in relation to environmental temperature and humidity and the design and capacity of the HVAC system.

b) A multidisciplinary team that includes at least representatives from infection prevention and control, facilities management, risk management, human resources, and SPD should establish the policies and procedures.

c) All staff working in the decontamination area/room should receive education and training in the dynamics of cooling the body and measures that can be taken to work comfortably while wearing PPE in the decontamination area/room.

Annex B
(informative)

Purchase considerations in selecting AERs and LCSPSs

Information about an AER or LCSPS considered for purchase for cleaning, disinfecting, or liquid chemically sterilizing flexible and semi-rigid endoscopes should be previewed by a committee that includes risk management, infection prevention and control, nursing, endoscopy, and sterile processing personnel. Cost is important but patient safety should always be the overriding factor when choosing any type of medical device. Cost considerations include the following:

a) purchasing cost;

b) cost of engineering controls such as dedicated exhaust, gas monitoring equipment, and cost of installation;

c) cost per cycle, including expenditures for service, support, energy, and disinfectants and other consumables; and

d) cost of initial and ongoing personnel education, training, and competency verification.

The following are considerations in the evaluation and selection of AERs and LCSPSs prior to purchase. Regardless of the features, when looking to purchase an AER or LCSPS, facilities should consider the following:

a) Is it FDA-cleared?

   — Review the manufacturer's written IFU.

   — Acquire and review white papers and other literature on the specific model/type of AER or LCSPS.

   — Can the institution follow all requirements of the IFU?

b) Does the system provide a suitable processing outcome, i.e., liquid chemical sterilization or high-level disinfection of devices as determined to be preferred or required by the facility's medical staff?

c) Can the AER or LCSPS process the types of endoscopes currently in inventory?

   — Has the manufacturer provided a list of each make and model of endoscope that can be processed?

   — Has the endoscope manufacturer validated the use of an AER or LCSPS with its endoscope(s)?

   — How will the AER or LCSPS manufacturer provide updates for new endoscopes that are introduced to the market after the purchase of the equipment, and how will the AER/LCSPS process the new endoscopes?

   — What type and how many different connectors/adapters are needed and how are they processed and maintained?

   — Can the endoscope and endoscope components be effectively processed with the AER/LCSPS (e.g., the elevator guide wire channel of some duodenoscopes might not be effectively disinfected by most AERs and this step should be performed manually)?

   — Are model-specific processing protocols from the endoscope and the AER/LCSPS manufacturers compatible?

d) What accessories can the AER or LCSPS process?

- Is the AER or LCSPS cleared by the FDA to process any of the peripheral endoscopy accessories currently in the inventory?

e) Is the LCS/HLD solution that is used in the AER/LCSPS FDA-cleared?

- Can more than one type of LCS/HLD solution be used in the model?

f) Is there sufficient space in the area for the unit?

g) What utilities and specifications are needed?

h) Does the processing area need any room or air monitoring while the AER or LCSPS is in operation?

i) Is an air handling system, such as a fume hood, needed?

j) If the AER or LCSPS has cleaning claims, is it clear how those claims are applied to the current practice?

k) What is the recommended preventive maintenance? Who is certified and available to perform the maintenance?

l) What is the servicing frequency and who is responsible?

m) Does the equipment monitor flow or pressure of fluids and/or air for endoscope channel flushing?

n) Are there rinse cycles that follow the cleaning and LCS/HLD cycles? Are these cycles followed by an air purge to remove excess fluid?

o) What are the AER's cycle time parameters?

p) Does the LCS/HLD processing equipment have a self-disinfection cycle?

q) Does the LCS/HLD processing equipment have a notification alarm for dirty or clogged filters?

r) Are the physical parameters for each cycle recorded in a print or electronic record?

s) Does the LCS/HLD processing equipment automatically detect chemical supply levels and alert the user when replacement is needed?

t) Can the facility meet the utility requirements called for, such as water quality, temperature, and pressure?

u) Are instructions of neutralization methods for chemicals to be used in the AER provided in IFU, if required? (See Annex H)

Annex C
(normative)

Reference material for repairs

This Annex is intended to provide sections of the key regulations and standards related to repair and servicing of flexible endoscopes and highlight the facility responsibilities. This Annex also covers qualification considerations for repair providers.

C.1 Repair of flexible endoscopes

CFR §482.41(d)(2): "…equipment must be maintained to ensure an acceptable level of safety and quality" if the facility is to meet CMS's condition of participation.

- The equipment is needed for day-to-day operations.
- The equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades.
- Equipment maintenance policies, procedures, and programs, as well as specific equipment maintenance inventories, activities, and schedules, fall under the purview of the hospital's clinical maintenance personnel, safety department personnel, or other personnel who have been assigned responsibility for equipment maintenance by hospital leadership.
- The health care facility is in compliance with the regulation when it follows the manufacturer-recommended maintenance activities and schedule, or the equipment is maintained in accordance with an alternative equipment management program based on accepted standards.

ANSI/AAMI EQ56:2013, Recommended practice for a medical equipment management program [8]:

- "The health care organization should develop standard procedures that delineate its expectations when repairs are made to its equipment." (8.1.1, Rationale)
- "Equipment users need to know how to obtain repairs on the equipment they are using. This minimizes the probability of equipment being used that is not in good repair and may be potentially dangerous to either the user or a patient. (8.1.1, Rationale)
- "The health care organization shall establish and implement policies for the removal from service of equipment determined to be unsafe …" (8.4)

AORN 2018(e), Guideline for cleaning and processing flexible endoscopes and endoscope accessories, Recommendations VII and X [40]:

- **VII.d. "**Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced."
- **VII.d.1** "Medical equipment being sent for repair must be decontaminated to the fullest extent possible and a biohazard label attached before transport."
- **X.a** "Records related to flexible endoscope processing should include:
    - "The disposition of defective items or equipment.
    - "The maintenance of water systems, endoscopes, and endoscope accessories, and processing equipment."

C.2 Loaned flexible endoscopes

ANSI/AAMI EQ56:2013 [8]

5.3 Non-hospital owned equipment

“Non-hospital-owned equipment is any equipment used in, but not owned by, the facility. These devices include physician or contractor owned, leased, rented, demonstration, loaned, and patient-owned equipment. Equipment in this category still needs to meet all of the sections of this standard. The maintenance history and culture history of these devices are often unknown. A facility is still liable for equipment used in that facility and needs to ensure that it is safe to use, able to be located for recalls, and properly maintained.”

At acceptance of a loaned endoscope:

1) The owner shall provide repair and maintenance history of the device.

2) The owner shall provide culture data if culturing has been performed.

3) The device shall be entered into the facility database and tracked as if the device were owned by the facility.

4) The device shall be processed per the facility’s policies in accordance with the manufacturer’s IFU.

At return of the loaned endoscope:

1) Information concerning the function of the endoscope shall be provided to the owner and receipt verified.

2) Culture information should be provided to the owner and receipt verified if it exists.

3) The device shall be reprocessed per the facility’s policies in accordance with the manufacturer’s IFU prior to return.

C.3 Qualification considerations for repair providers

Repair providers should have at least the following qualifications and abilities:

— The engineering capabilities to discern processes, reverse engineer parts, and validate components;

— A quality management system (QMS) for service processes and employee skills;

— The ability to perform durability testing of processes and components;

— The ability to perform analyses of trended repair needs, including cause, effect, and prevention;

— Documented cost-reduction programs to address equipment damage trends.

Annex D
(informative)

Manufacturer's written instructions for use (IFU) conflict management

The selection of an appropriate processing method is complex because of the huge variety of reusable items and manufacturers and the wide range of available processes. There are diverse and often conflicting recommendations for handling supplies and equipment and for controlling biological hazards through decontamination, disinfection, and/or sterilization methods. These diverse recommendations have been provided to health care personnel by professional organizations, government agencies, device, equipment, and chemical manufacturers' written instructions for use, as well as by evidence-based literature/research, consultants, and educational speakers. There is clearly a need for consistency in guidelines, with supporting rationale, for processing techniques.

Prior to purchase or use of reusable medical devices, or changes in equipment, suppliers, or chemicals, the following should be completed:

a) Review the device, equipment, and chemical manufacturers' written IFU.
   - Identify variations in process instruction.
   - If conflicting instructions are identified, contact each manufacturer to request clarification or explanation and/or modification of the IFU:
     - Clarification should be provided in writing, preferably on company letterhead.
     - The manufacturer's communication should be dated and include the name, job title, and signature of the person responding.
     - At minimum, clarifications may be provided in email.

b) Review applicable standards and guidance documents.

When there is a conflict between two or more manufacturers' written IFU, it is recommended that the healthcare facility conduct a risk assessment and provide specific recommendations and guidance for the processing of the device(s) with the conflicting IFU. The following should be considered and completed:

1) Contact the manufacturers of the products being used (e.g., endoscopes, AER, cleaning agents).

2) Utilize a team approach for review and risk assessment. Designate the members of the team, preferably a multidisciplinary team with representation from each affected area (e.g., infection prevention and control, sterile processing, end users, procurement, risk management, and the device manufacturer). The team should:
   - review the IFU and the literature;
   - review standards and regulations from each applicable organization;
   - create standard operating procedures and process improvements; and
   - conduct a risk and/or needs assessment.

3) Create a standard operating procedure for each phase of the device life cycle.

4) Complete product quality assurance testing and/or product verification testing on the created standard operating procedures.

Annex E
(informative)

Endoscope visual inspection

E.1 General considerations

This Annex describes methods and areas of an endoscope to consider when visually inspecting it for defects/damage, moisture or retained items.

E.2 Overview

Each time an endoscope is handled, it should be inspected for any damage. It is important to be able to identify damage to the endoscope that could compromise patient safety and endoscope integrity. Current methods used to identify damage can range from inspection with the unaided eye to the implementation and use of magnification and borescopes. Endoscopes should be inspected with proper lighting and magnification. This is supported by standards and guidelines. ANSI/AAMI ST79:2017 states: *"Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye."* [17]

The FDA supports visual inspection of any medical device. The FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff" (updated in 2017) [328] states the following: *"All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device. Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail."*

E.3 Anatomy of an endoscope

The visual inspection process should be broken down using the anatomy of the endoscope (see Figure E.1). The following points are items that should be visually inspected during processing and prior to each case.

NOTE This is an example of a flexible endoscope. Not all endoscopes are identical in design.

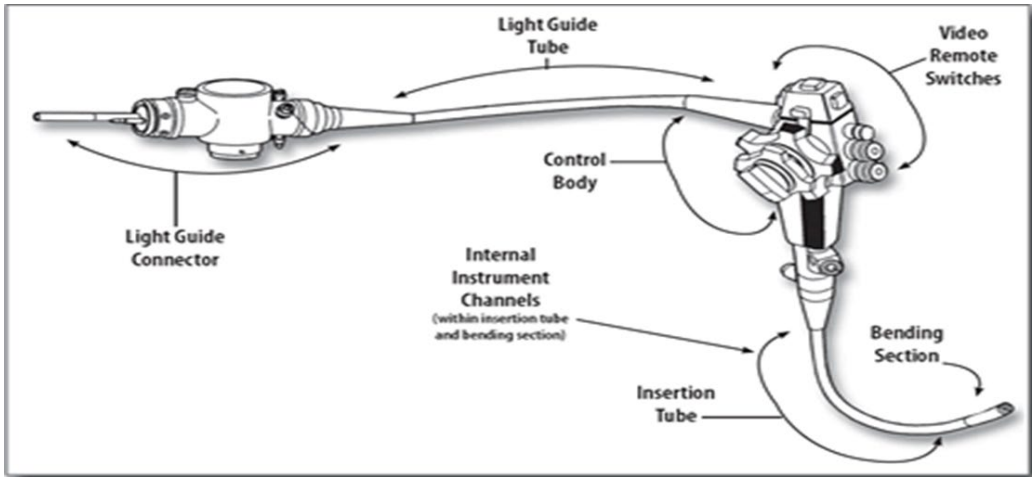

Figure E.1—Inspection of an endoscope using the unaided eye or magnification

{SOURCE: Educational Dimensions. Available: https://www.educationaldimensions.net/eLearn/endoscope/anatomy.php.}

Figure E.2 provides an example of a duodenoscope. Not all duodenoscopes are identical in design.

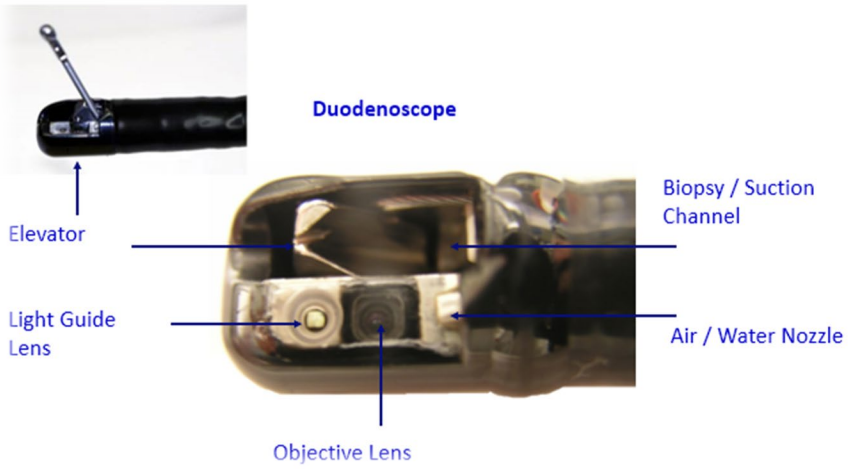

Figure E.2—Anatomy of endoscope elevator mechanism of duodenoscope distal end

E.4 Visual Inspection process

The minimum standard of care for a visual inspection process is using the unaided eye. Inspection aids, such as hand-held magnifiers, lighted magnifiers, and/or borescopes, additional inspection should be used. Magnifiers and borescopes are used to inspect where the unaided eye cannot see, including assessment for defects in functionality, damage including pitting, stains, repair needs, missing or damaged components, imperfections, retained items, compromised integrity of materials and seals, and residual moisture in or on the endoscope. An endoscope may be removed from service based upon inspection findings and potentially in accordance with the endoscope manufacturer's IFU.

Manufacturers of endoscopes suggest that health care personnel visually inspect endoscopes for defects and, if any are found, send the endoscope for recleaning or repair. Unfortunately, many IFUs do not provide much direction on where and what to look for when it comes to defects. Recent articles have suggested that the use of the unaided eye for inspecting endoscopes is not enough and the use of enhanced visual inspection is helpful in ensuring that any endoscope is as defect-free as possible (Barakat, 2018 [79]; Thaker, 2018 [309]; Galdys, 2019 [158]; Ofstead, 2017 [244] [246]; Ofstead, 2018 [242]; Rauwers, 2019 [262]; Alfa, 2020 [63]).

Facilities can create their own index of pictures, starting with a new endoscope and taking pictures of key areas so staff can be trained on what they are looking for in the visual inspection of each model/type of endoscope used at the facility.

Based on standards, guidelines, manufacturers' written IFU, and articles both peer and non-peer reviewed, visual inspection for an endoscope should include:

1) Unaided eye, no magnification.

2) Enhanced visual inspection, using one or more of the following, for external surfaces:

    a) Hand-held magnification;

    b) Tabletop/swivel arm magnification;

    c) Lighted magnification;

    d) USB/computer supported magnification.

Enhanced visual inspection using a borescope can be used for internal channels and ports.

E.5 Implementation of visual inspection of endoscopes

The unaided eye is the first step in optical inspection but by itself it cannot see all the possible defects of an endoscope. Health care personnel should inspect the channel openings, distal tip, and elevator recess of endoscopes and can inspect the instrument/suction channels of endoscopes and the internal lumens of other medical devices to determine if there are any signs of damage or retained debris. Magnification and a borescope are tools to help ensure that endoscopes are without defects. The best way to implement this type of enhanced visual inspection is to do a gap analysis/risk assessment for each endoscope and its process, then use ANSI/AAMI ST90 [18] as a guidance document to start implementing visual inspection of each endoscope.

E.6 Borescope inspection of an endoscope

When using a borescope, there are many areas in an endoscope to inspect for damage or retained debris, including the instrument/suction channel, channel openings/valve housings, distal tip, and forceps elevator recess.

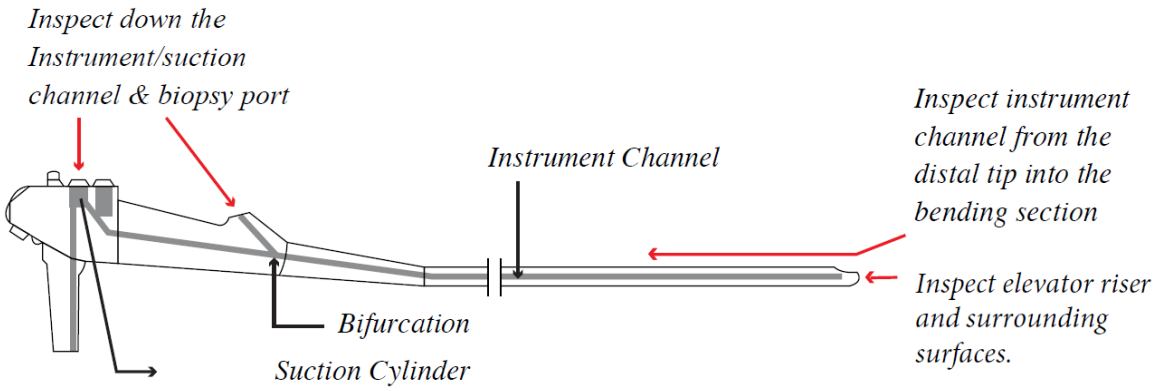

Figure E.3—Areas to inspect for damage on endoscope

NOTE Red arrows indicate methods of inspection, black arrows refer to areas of the endoscope.

{SOURCE: Healthmark, Inc.} [171]

E.7 Damaged adhesive

Adhesive is used to form a water-tight seal at the distal end, including around the lens, light guide, air/water nozzle, and fixed distal endcap for side-viewing endoscopes. Damaged or missing adhesive can lead to ingress of fluids, soils, or bioburden. Carefully visually inspect the distal end and remove from use any endoscopes with damaged or missing adhesive.

E.8 Inspection of components

E.8.1 Light guide connector, light guide tube, control body (including valves and switches)

These areas can be inspected with the unaided eye or with lighted magnification for retained soil, chemical damage, functionality, and defects. Damage should be noted in the repair records for the endoscope, and an evaluation of functionality should be performed. Any retained debris would warrant recleaning of the device. Chemical damage such as peeling creates a surface that is difficult if not impossible to disinfect properly; therefore, the component should be taken out of service and sent for repair.

- Angulation Control Knobs
- Free / Engage Lever
- Suction
- Air / Water Valve (clean lens)
- Switch Unit (buttons)
- Biopsy Port

Figure E.4—Control body (including valves and switches)

E.8.2 Insertion tube

Inspection of the insertion tube on the outer part of the endoscope can be performed with the unaided eye and with magnification.

Insertion tube defects include the following:

a) Coating peeling, tearing, ripping, or scratching (Figures E.5 and E.6). If seen, the endoscope should be sent for repair.

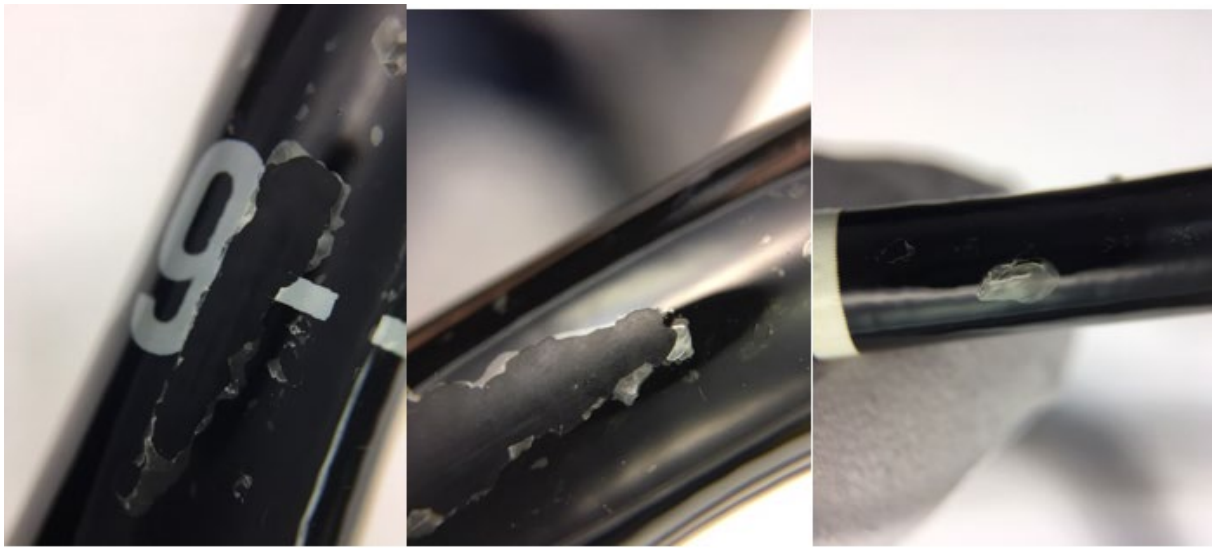

Figure E.5—Examples of insertion tube peeling and scratching

Figure E.6—Additional example of insertion tube defects

b) Dents, crush marks (Figure E.7): Denting and crush marks can signal damage to inner components, such as restricted channels, fiberoptic breakage, and angulation component damage.

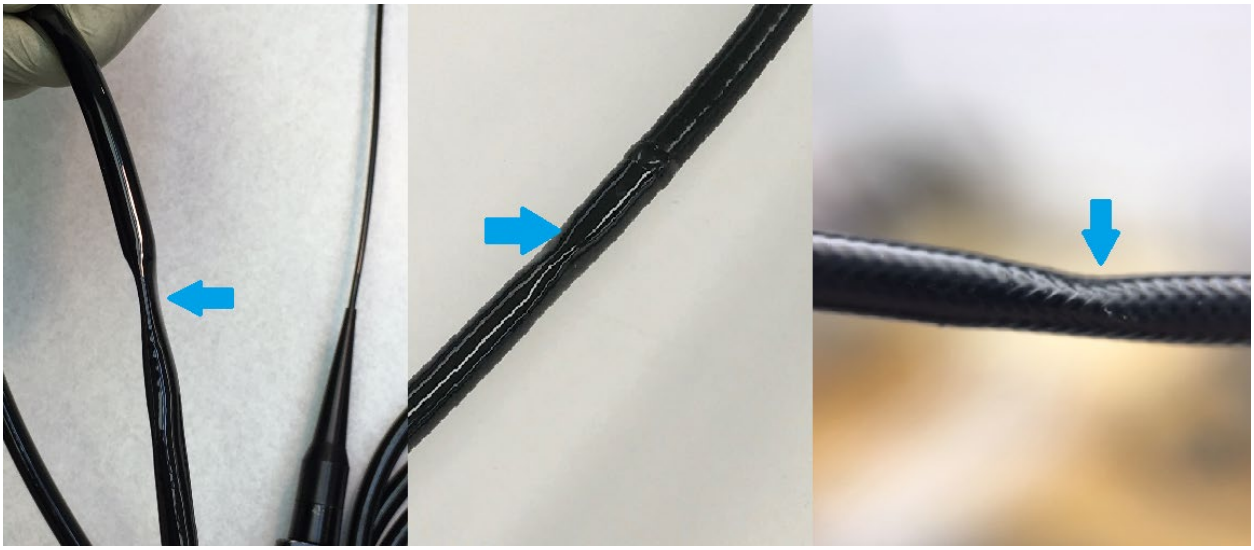

Figure E.7—Examples of denting and crush marks

c) Buckling (Figure E.8): Buckling occurs when the inner coil of the insertion tube becomes compromised and the polymer coating separates from the inner coil of the insertion tube or light guide tube, which can damage inner components.

Figure E.8—Examples of buckling

E.8.3 Biopsy port

The biopsy port of the endoscope can be inspected with a borescope to properly inspect inside the lumen/channel. Any crack, nick, chip, loosened part, or other damage seen in this area, even if it seems minor, can trap soils, and have an impact on effective processing.

Figure E.9—Biopsy port

E.8.4 Distal tip

The bending section and distal tip should be inspected with magnification. To inspect the biopsy channel terminus at the distal tip, a correctly sized borescope can be used to look into the lumen.

Distal tip defects include the following:

a) Cracked or damaged distal c-cover (Figure E.10). This type of damage can cause sharp edges or pieces that could separate from the endoscope.

Figure E.10—Examples of cracked or damaged distal c-cover

b) Cracked or chipped objective or light guide lens (Figure E.11). This type of damage can cause sharp edges or glass fragments to come loose in the patient.

Figure E.11—Examples of cracked or chipped objective or light guide lens

c) Residue buildup or staining (Figure E.12 and E.13). Using an endoscope that has chemical buildup from improper rinsing or one that has residue buildup can cause patient infection or cross-contamination.

Figure E.12—Examples of residue buildup or staining

d) Laser burns. Laser burns can cause melted distal end components, sharp edges, and an area to harbor microorganisms.

e) Nozzle loose or damaged. This type of damage can cause patient injury due to sharp edges or improper irrigation, or the nozzle could fall out in the patient if not properly secured.

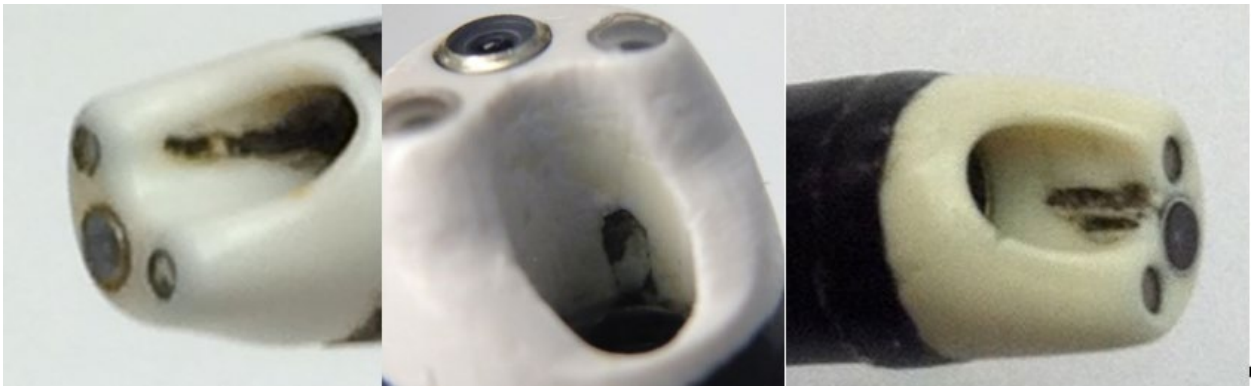

Figure E.13—Examples of residue buildup or staining

The duodenoscope provides inspection challenges because the distal tip has working parts. The use of the unaided eye alone is insufficient for proper inspection. Magnification, preferably lighted, should be used to inspect these areas of the endoscope. Areas to inspect are the elevator wire area around both sides of the forceps elevator, the air/water nozzle area, the light guide, and the objective lens.

E.8.5 Bending section

Bending section defects include the following:

a) Bending rubber glue joint separation (Figure E.14). This is an area that will harbor patient debris and might have sharp edges that could injure the patient. If a bending joint separation is found, remove the endoscope from service.

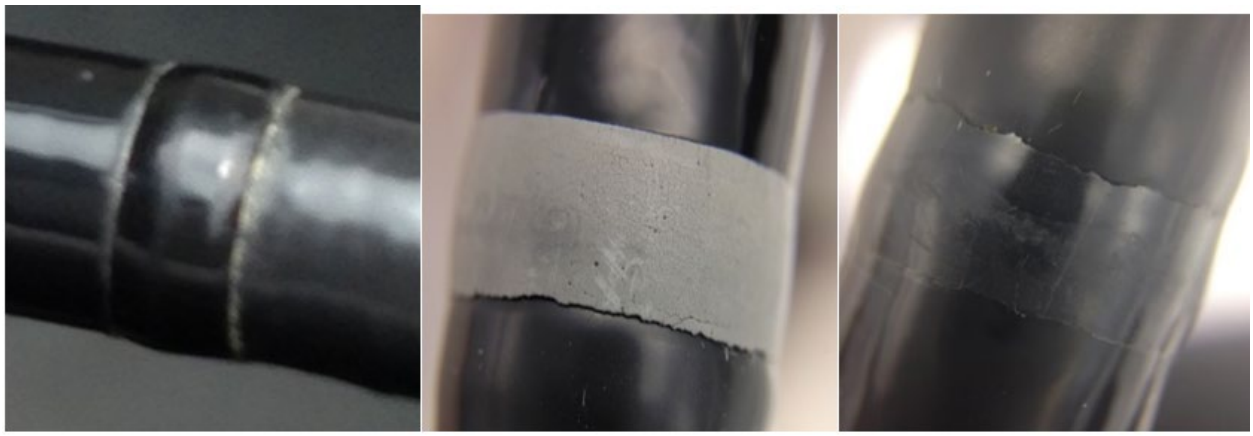

Figure E.14—Examples of bending section rubber glue joint separation

b) Cracks in glue joints (Figure E.15). This is an area that can harbor patient debris and have sharp edges that could injure the patient. Severe cracks can cause the glue joint to separate from the distal end.

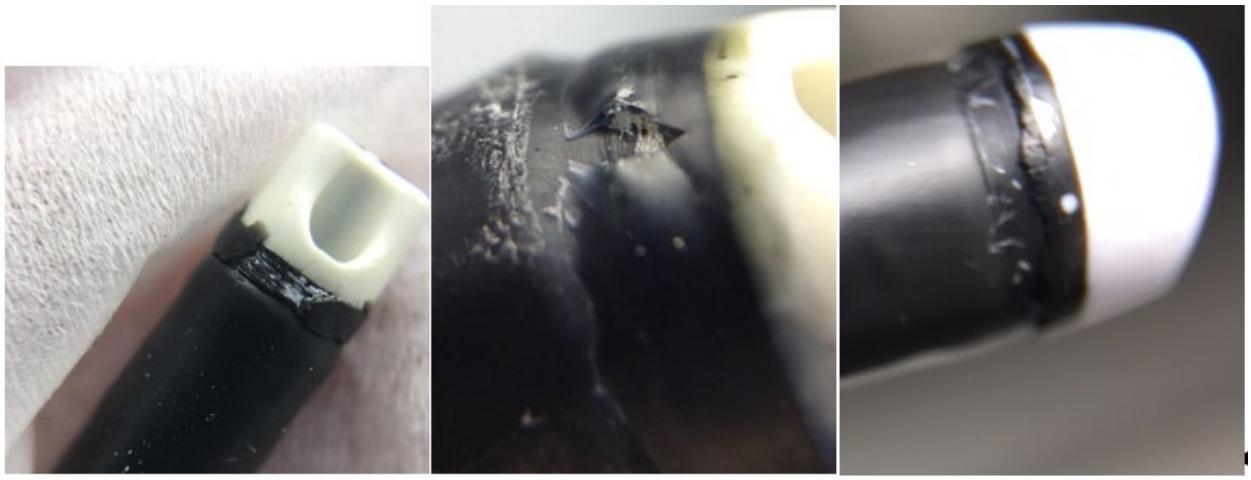

Figure E.15—Examples of cracks in glue joints

c) Bending rubber. Visually inspect the bending rubber for cuts or punctures (Figure E.16).

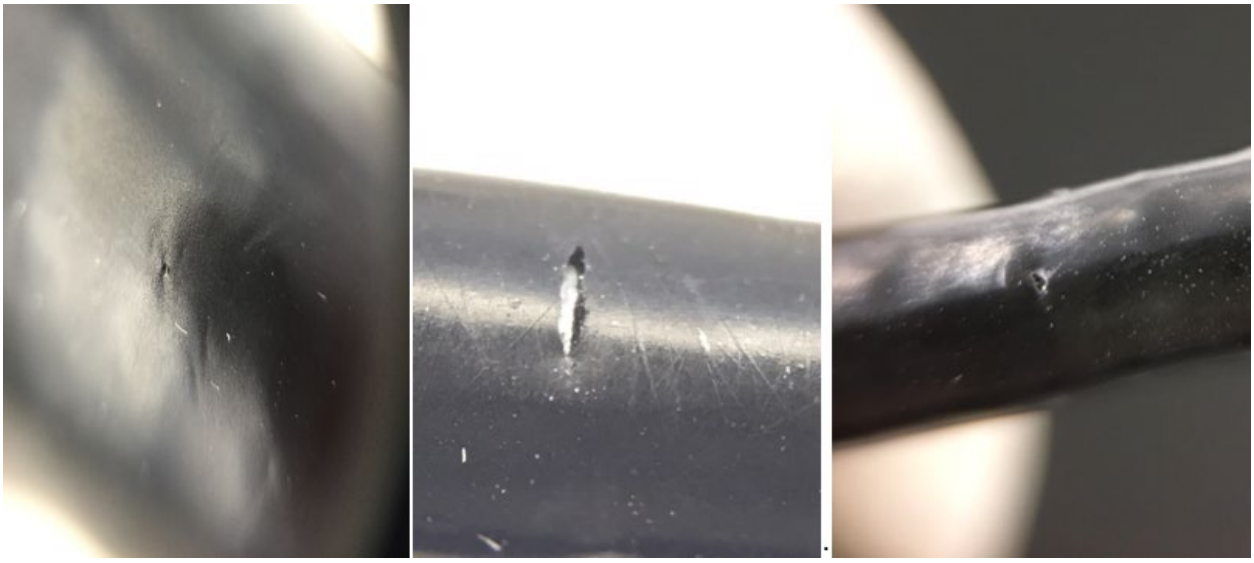

Figure E.16—Examples of cuts or punctures

d) Articulation (Figure E.17). Improper or irregular articulation can result from worn or damaged inner angulation components, and could result in patient injury, or prevent the user from being able to properly perform the procedure.

e) Stiff controls. Stiff controls might be an indication of fluid invasion or worn/damaged inner components and could prevent the user from being able to properly perform the procedure.

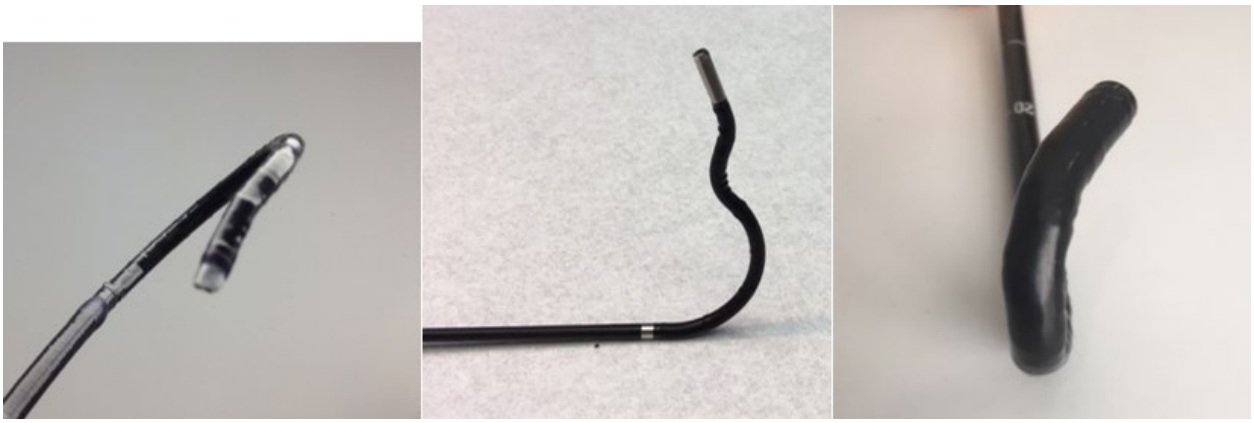

Figure E.17—Examples of articulation

E.8.6 Channel

When a borescope inspection is performed, it is recommended that the length of the instrument/suction channel be inspected from the biopsy port to the distal tip. Depending on the length of the borescope, this is accomplished by either inspecting the entire length of the channel in a single direction or by inspecting from each end to the center. The channel should be inspected for damage, debris, simethicone, retained items such as sutures, and moisture. If damage is found, the endoscope should be removed from service according to the health care facility's policy and sent out for repair. If retained items are noted, the endoscope should be recleaned and reinspected to determine if the items are still found within the lumen. If moisture is found (Figure E.18), the facility policies for drying should be adjusted to ensure that endoscopes are dry prior to storage.

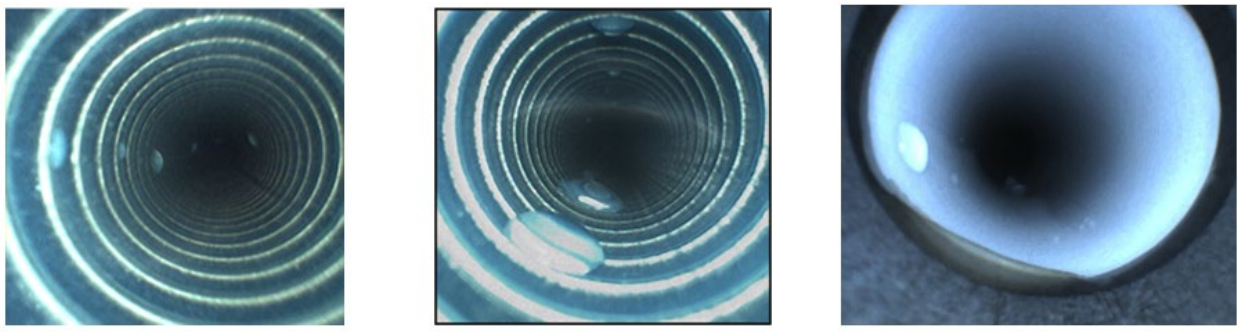

Figure E.18—Examples of moisture

Annex F
(informative)

User verification of cleaning processes[1]

F.1 General considerations

Verification of a cleaning process consists of:

a) defining a cleaning process that can be accomplished with comprehensive personnel training and verified through observation that it can be followed consistently; and

b) implementing a testing system that verifies adequate, consistent results.

Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on device manufacturers' written IFU and published recommended practices or guidelines. The second concerns measuring and evaluating residual contaminants on medical devices after applying the established cleaning process.

FDA has not reviewed the effectiveness of cleaning verification assays; rather, the manufacturers of cleaning verification assays develop their own methods and criteria for assessing the effectiveness of their products.

The medical device manufacturer must validate that the device can be cleaned and disinfected or sterilized adequately to allow the device to be reused and provide the information in the written instructions for the handling, cleaning, disinfection, packaging, and sterilization of medical devices in a health care facility. (ANSI/AAMI/ISO 17664 [7], AAMI TIR12 [20] and AAMI TIR30 [21] address the issues related to manufacturers' validation testing for cleaning of medical devices.)

Medical device manufacturers should be familiar with cleaning, disinfection, and sterilization technologies used in health care facilities and with the kinds of soil and microbial contamination encountered as a result of patient use. Users establish an appropriate cleaning policy and procedures for the reusable medical devices they process. The procedures should be based on the validated recommendations of the device manufacturer and the cleaning solution manufacturer, published data on the cleaning efficacy for the medical devices (if available), and published recommended practices or guidelines.

Cleaning efficacy tests are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the clinical soil so that the subsequent disinfection or sterilization process can be effective.

Ideally, cleaning verification should include:

a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and the inner housing and channels of medical devices;

b) testing the cleaning efficacy of equipment and the cleaning process; and

c) monitoring key cleaning parameters (e.g., temperature). Manufacturers provide users with such tests so that medical devices can be tested directly after cleaning in a way that will not damage the device or require recleaning.

[1] Adapted from ANSI/AAMI ST79:2017, Annex D.

A more objective and sensitive method than visual inspection is to measure the levels of organic soil on the cleaned device. There are commercially available tests that allow users to rapidly verify that adequate cleaning has been performed.

A facility's quality assurance program should include ways to verify that the cleaning equipment is working properly and that the cleaning process is effective. Automated cleaning equipment should be tested upon installation, per the manufacturer's written IFU or each day that it is used if frequency is not specified, on all cycles used after repairs, and when changing to a new type of cleaning solution. The automated cleaning efficacy test and equipment manufacturers' written IFU should be followed.

Simple monitoring tools that provide objective, real-time quality control checks can help to verify staff competency and compliance with cleaning guidelines.

Basic components of user verification of cleaning efficacy are:

a) select an appropriate rapid, easy-to-use test that represents a soil marker relevant to the devices used;

b) establish reasonable benchmarks for the level of cleaning that can be achieved; and

c) determine frequency of use based on facility factors (e.g., types and condition of devices, etc.)

F.2 Markers (analytes)

Cleaning is the removal of organic material (e.g., patient secretions), inorganic material (e.g., salts), and microbial contamination (acquired from the patient procedure, the environment or during handling) to ensure that adequate disinfection or sterilization can be achieved, thereby making the device safe for subsequent use on patients. Published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that one or more of the following markers are useful for benchmarking purposes (Washburn et al., 2018 [372]; Sethi et al., 2017 [290]; Alfa et al., 2014 [59]):

a) protein;

NOTE 1 Protein detection by chemical reaction interpreted as a visible color change or a quantitative measure of residue (utilizing a color chart [semi-quantitative] or photometric device). Samples may be collected by swabbing, flushing, or direct application of reagent.

b) carbohydrate;

c) hemoglobin (blood); and

NOTE 2 Hemoglobin detection by chemical reaction. Interpreted as a visible color change or a quantitative measure of residues. Samples may be collected by swabbing or flushing.

d) adenosine triphosphate (ATP).

NOTE 3 Detection of ATP by chemical reaction. Measurement of fluorescent light reported as a numeric value. Samples can be collected by swabbing or flushing.

Different cleaning verification methods have benchmarks that have been established and, in some cases, validated by the cleaning indicator manufacturer or through independent studies. Facilities should determine whether the benchmarks pertain to the tests they intend to use based on the endoscope type, component tested, and whether the units or measurements are applicable.

Realistic benchmarks depend on what can be achieved by routine cleaning and the limit of detection of the method used. Data indicate that for flexible endoscopes that have been cleaned after use on patients, the average level of soil markers in the suction/biopsy channel are as follows (Alfa et al., 2013 [55] [60] [61], 2012 [58]):

e) protein, <6.4 µg/cm^2;

f) carbohydrate, <1.8 µg/cm^2;

g) hemoglobin, <2.2 µg/cm^2;

h) sodium ion, <1 µmole/cm^2;

i) endotoxin, <2.2 EU/cm^2;

j) bioburden, <4 $\log_{10}$ CFU/cm^2;

k) ATP, <22 femtomoles/cm^2.

NOTE Research has found that reduced protein and bioburden cut offs can be achieved.

F.2.1 ATP

ATP has been validated against other common markers including protein, carbohydrate, and bioburden. (Alfa et al., 2002 [57], 2012 [58], 2013 [55] [60] [61]).

The unit of measure for ATP is femtomole (1 X 10^{-15} mole). An ATP monitoring system converts ATP to light, and the amount of femtomoles of ATP present in a sample is detected by a measuring device that can read the amount of light generated by the ATP. The measuring device gives a readout of that light value in Relative Light Units (RLUs), which is directly proportional to the amount of femtomoles of ATP present in the sample. As different systems are available with various measuring devices, a benchmark value of <22 femtomoles of ATP/cm^2, has been correlated to the equivalent values of other markers including the established protein benchmark of 6.4 µg/cm^2 (200 RLU converts to 22 femtomoles/cm^2 for the system cited in Alfa, 2013a [55]; Alfa, 2014 [56] [59]; Alfa, 2013b [60]).

For the specific ATP system cited in the literature, 200 RLU was correlated to the equivalent values of other markers. For that system, the ATP values can be converted from 200 RLU to femtomoles/cm^2 by using the conversion factor of 9 RLUs/femtomole of ATP which provides a correlated value of 22 femtomoles of ATP/cm^2 (196 RLUs/cm^2 divided by 9 femtomoles of ATP/RLU). Other ATP systems might have different conversion factors.

NOTE ATP test manufacturers use varying scales. Check with the ATP test manufacturer for the recommended benchmark or the femtomole-to-RLU conversion factor.

F.2.2 Protein

A number of methods for protein detection and quantification have been developed and validated for a variety of purposes, including cleaning verification testing. These include:

a) Pyrogallol Red method (Fujita et al., 1983 [156]): This is a color reaction between Pyrogallol Red-molybdate complex and protein. The complex binds to basic amino acid groups of protein molecules. The increase in absorbance is directly proportional to protein concentration in the sample. Results can be read visually for color change (qualitative test) or using a color interpretation chart (semi-quantitative test), or with a spectrophotometer for quantitative results.

b) Bromophenol Blue method (Flores et al., 1978 [150]): Protein is detected using the pH indicator Bromophenol blue. At a low pH Bromophenol blue is yellow in the absence of protein. Presence of a protein slightly increases the pH of the solution. This increased pH causes Bromophenol blue to change its color from yellow to greenish blue. This color change can be read visually for color change (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

F.2.3 Hemoglobin

Peroxidase test method (Geissler et al., 1977 [162]; Liem et al., 1979 [206]): Relies on the peroxidase-like activity of hemoglobin in blood to catalyze the oxidation of some compounds in the presence of hydrogen peroxide to yield colored substances, which are easily detected. This reaction can show blood residues by a color change to blue. This color change can be read visually for color change (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

F.2.4 Carbohydrates

Glucose oxidase test method (Jakobsen, 1960 [182]): Specifically tests for glucose. This test is based on a sequential enzyme reaction**.** Glucose oxidase converts the glucose to gluconic acid and hydrogen peroxide. A second enzyme, peroxidase, catalyses the reaction of peroxides to produce a positive color change. This color change can be read visually (qualitative test), compared to a color chart (semi-quantitative) or with a spectrophotometer for quantitative results.

F.3 Cleaning verification tests for users

There are a number of commercially available validated test methods for rapid detection of organic residues on flexible endoscopes.

Ideally, cleaning tests for in-use verification of medical device processing should be:

a) rapid;

b) easy to perform;

c) sensitive (i.e., meet realistic benchmarks);

d) accurate;

e) repeatable;

f) free of interfering substances; and

g) robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine processing areas).

To be of most utility to users, cleaning verification tests should enable users to quickly test medical devices directly after cleaning and in a way that will not damage the device or require recleaning. Moreover, easy-to-perform tests are also needed to verify the functionality of automated washers. Such tests should not lead to the introduction of interfering or extraneous materials that could remain on medical devices post-testing.

For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks once these benchmarks have been defined.

F.3.1 Verification tests for ultrasonic cleaners

a) **Test for cavitation in ultrasonic bath:** Indication can be physical measurement or visual assessment.

b) **Test for soil removal (external) in ultrasonic bath:** Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

c) **Test for soil removal (internal within lumens) in ultrasonic bath:** Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.

F.3.2 Verification test for mechanical washers

a) **Test for soil removal:** Indication is visual assessment or absence of marker on a coupon placed in the washer.

F.4 A program for verification of the efficacy of the manual cleaning during endoscope processing: An example

The purpose of verifying manual cleaning efficacy is to ensure that the manual cleaning step performed during endoscope processing is consistently performed correctly according to established thresholds. Implementation of a cleaning verification program should be part of a complete endoscope processing quality control program.

A manual cleaning verification program has two goals.

1) **Quality control.** Is each endoscope effectively cleaned before HLD or sterilization? In this case, the efficacy of the manual cleaning process is verified for every endoscope after every use.

2) **Process control.** Is the manual cleaning process under control? This approach verifies the efficacy of manual cleaning for a percentage of endoscopes over a specified number of processing cycles to assess if the manual cleaning process is under control. This approach can highlight undesirable variability in the efficacy of the manual cleaning process. Verification data can be used to assess if changes or improvements in processing procedures are working as intended (e.g., reducing variability in the number and frequency of manual cleaning failures).

A comprehensive manual cleaning verification program is not a substitute for other quality control measures (e.g., culturing of endoscopes after processing by high-level disinfection or sterilization).

A complete cleaning verification program contains the following components:

1) Establish policies and procedures

Policies and procedures for a manual cleaning verification program should include the following:

   a) Designation of a person or department responsible for defining, establishing, and implementing a routine manual cleaning verification program.

   b) Designation of a person or department responsible for ensuring that all personnel implementing the cleaning verification program are adequately trained and that, at a minimum, annual competency verifications are performed.

   c) A method for verification data capture and storage.

   d) A process for routine review and analysis of verification data.

   e) A process for addressing cleaning verification failures.

2) Identify which endoscope types will be routinely monitored

   a) Identify high-risk endoscopes (see 3.31). Additional endoscope types may be added to the high-risk category depending on individual facility manual cleaning performance. Evidence of endoscope-associated infections due to cross-contamination or outbreak situations could result in the temporary addition of any endoscope type to the high-risk category.

   b) Identify those endoscopes that are not high-risk.

   c) Ideally, all endoscope types should be included in a cleaning verification program.

3) Determine test points for each type of endoscope

Test points should include at a minimum:

   a) suction/biopsy (working) channel;

b) elevator mechanism if present;

c) elevator channel if present.

Consider periodic assessment of irrigation accessories, the external distal tip of the endoscope, the control handle, valve housings, the biopsy port, and reusable valves (buttons).

4) Determine pass/fail thresholds

a) Pass/fail thresholds should be pre-determined before verification testing begins.
b) Pass/fail thresholds vary depending on the cleaning verification technologies used. The manufacturer's written recommendations for pass/fail thresholds should be followed.
c) Pass/fail thresholds should be established related to the area of the endoscope sampled and should be validated for use with endoscopes.
d) Health care facilities may establish pass/fail thresholds for their unique facilities. These thresholds should be based on solid statistical methodology.

5) Frequency of testing

Cleaning verification should take place after manual cleaning and before high-level disinfection or sterilization. The frequency of verification testing depends on the type of endoscope (see 11.2.4.2 for risk assessment):

a) High-risk endoscopes should be monitored after every use.
b) Those endoscopes that are determined NOT to be high-risk shall be verified:
   — when new endoscopes are purchased;
   — when loaned endoscopes are received for temporary use; and
   — at established intervals (e.g., after each use, daily) or, at a minimum, at a statistically significant frequency based on the number of procedures.

Endoscopes should be randomly selected for verification testing to avoid repeated testing of the same endoscopes.

The frequency of testing should be increased if tests done as process controls identify cleaning failures for a substantial proportion of endoscopes. If the process is not under good control, then the tests should be done every time for quality control until cleaning consistently succeeds at removing soil.

6) Data analysis

Verification data should be reviewed on a regular basis so that adverse issues can be addressed in a timely manner. Examples of how cleaning verification data can be used include the following:

a) verification that education and training of personnel responsible for manual cleaning of endoscopes is effective;

b) verification of processing technician competency in manual cleaning procedures. Managers should review verification data for each processing technician at least quarterly;

c) identification of ongoing systematic errors in the manual cleaning process;

d) identification of aging or damaged endoscopes that are difficult to clean;

e) identification of other factors that may be contributing to problems with cleaning effectiveness, such as sitting used during lengthy procedures, substantial bleeding or secretions, a lack of adequate point-of-care treatment, necrosectomy, or delayed reprocessing;

f) verification that an endoscope has met a pre-determined threshold for cleanliness and is ready for high-level disinfection or sterilization (quality control);

g) verification that the manual cleaning process is under control (process control);

h) assessment of whether changes or improvements made to manual cleaning procedures are effective in reducing variability in the number and frequency of cleaning failures. Manual cleaning verification data cannot be used to verify that an endoscope has been adequately high-level disinfected or sterilized and is safe for use on a patient.

Annex G
(informative)

Effects of simethicone on flexible endoscopes

Simethicone is an anti-foaming agent and is the active ingredient in a variety of anti-gas medications. It consists of a silicon-containing polymer called polydimethyl siloxane, or dimethicone, and silicon dioxide. Simethicone is an inert substance that is very difficult to remove due to its hydrophobicity, and the drug formulation might contain additives such as sugars for flavoring or thickeners for viscosity. During an endoscopic procedure, simethicone drops might be injected into irrigation water bottles or directly into endoscope channels to reduce bubbles that can interfere with visualization. Clinical series demonstrate enhanced polyp and adenoma detection rates with use of simethicone for selected patients in whom adequate visualization otherwise cannot be achieved (Kutyla et al., 2018 [204]). According to endoscope manufacturers and the FDA, this off-label use of simethicone should be avoided (Olympus, 2018 [248]; Pentax, 2014 [252]; Fujifilm, 2013 [155]).

Multiple studies have documented the persistence of simethicone in endoscope channels, despite repeated cleaning and disinfection procedures (Ofstead et al., 2016 [239] [247]; Barakat, 2019 [80]; Ofstead, 2019 [234] [240] [241]; Van Stiphout, 2016 [365]). Simethicone can form crystal deposits that may occlude narrow lumens, such as the water-jet channel (Van Stiphout, 2016 [365]). Accumulation of these deposits can interfere with proper flushing of the channel during cleaning, increasing the risk of growth of microorganisms and biofilm formation. The sugars and thickeners present in the simethicone drug formulation might also contribute to growth of microorganisms. To further complicate matters, simethicone can be difficult to detect in flexible endoscopes. In one study (Barakat, 2019 [80]), researchers found a correlation between the concentration of simethicone used and the retention of observed water droplets. Endoscopes exposed to 0.5 % simethicone averaged 5.81 water droplets (±2.77), while endoscopes exposed to 1 % simethicone had 13.47 (±5.64) droplets and endoscopes exposed to 3 % simethicone had 17.3 (±6.61) droplets. A control group with water had an average of 6.3 visible droplets (±3.52).

The Canadian Association of Gastroenterology (CAG) reviewed the evidence of the effects of simethicone on endoscopes and published a Position Statement in 2018 (Benmassaoud and Parent, 2018 [91]). Although simethicone itself has not been associated with healthcare-associated infections, it might contribute to the formation of biofilms, which have been implicated in outbreaks of post-ERCP bacteremia. The CAG does not ban the use of simethicone during endoscopic procedures, but recommends following the endoscope manufacturers' IFUs, strictly adhering to high-level processing protocols, and considering the performance of regular microbial surveillance. The CAG also suggests that endoscopy units reconsider the routine addition of simethicone to the water during procedures, and, if it is used, using only the lowest effective volume.

In addition to the statement by the CAG, the major GI endoscope manufacturers recommend against the use of simethicone, citing the difficulties in removal of simethicone even when reprocessing instructions are followed. If used, the manufacturers also advise employing only the lowest effective concentration in the smallest amounts through the biopsy channel alone, and not in the wash bottle or through smaller inaccessible water flush channels. However, recent studies have shown that, even when used at very low concentrations, simethicone persists in endoscope lumens after reprocessing (Barakat, 2019 [78] [80]). Throughout this standard, emphasis has been placed on the importance of cleaning. Failure to perform satisfactory cleaning can result in disinfection or sterilization failure and outbreaks of infection (CDC, 2008 [109]). Disinfection and sterilization depend on the removal of both organic and inorganic materials.

Furthermore, the FDA has not approved the use of simethicone for use in bowel preparation (ASGE, Technology Assessment Committee, 2009 [28]. Multiple recalls of simethicone have taken place over the years, resulting from contamination with debris, yeasts, molds, and potential bacterial pathogens that exceeded the USP specification for maximum microbial content (Major Pharmaceuticals, 2019 [207]; Sutton, 2012 [305]; Drucker, 2008 [140]).

Annex H
(informative)

Safety considerations for high-level disinfectants and liquid chemical sterilants

This Annex is intended to provide important considerations in the use of liquid chemical sterilants and HLDs for endoscope processing and information on the characteristics of LCSs and HLDs and associated safety requirements.

The information provided in this annex was accurate at the time the standard was approved for publication. However, sterilization and high-level disinfection processes evolve over time, and FDA-cleared manufacturers' label claims and IFU change accordingly. Therefore, it is essential that health care personnel obtain up-to-date information for the products that they use or are considering using and refer to manufacturers' current label directions and written IFU.

If any eye contact should occur with any HLD or LCS, the eye should be rinsed immediately with plenty of water for at least 15-minutes; the eyelids should be held apart forcibly to ensure flushing of the entire eye surface.

H.1 Glutaraldehyde solutions

H.1.1 Introduction

Glutaraldehyde-based products are effective sterilants and disinfectants used primarily for medical devices that cannot be steam sterilized, particularly heat-sensitive, lensed instruments that are commonly subjected to high-level disinfection between patient uses. If used properly, glutaraldehyde-based products can be used without tissue irritation or other adverse health effects. However, dermatologic, respiratory, and ocular effects have occurred in overexposed personnel and skin sensitization has been reported with less pronounced exposure; therefore, adequate precautions should be taken when using glutaraldehyde-based products (Nayebzadeh, 2007 [219]; Takigawa, 2006 [307]; Ballantyne, 1995 [75]).

This section covers the properties and applications of glutaraldehyde; occupational exposure considerations specific to glutaraldehyde, including vapor monitoring and procedures for handling spills; and the disposal of glutaraldehyde solutions.

NOTE Glutaraldehyde is a major component of many LCS/HLD products. Chemical and toxicological properties are unique to any given chemical, so the properties of glutaraldehyde discussed here should not be generalized to other components that a formulation might contain. The product manufacturer should be consulted for further details on the formulation and for an SDS.

H.1.2 Properties and applications of glutaraldehyde

The biocidal properties of 2 % glutaraldehyde in alkaline aqueous solution were discovered in the early 1960s (Borick, Dondershine, and Chandler, 1964 [96]). This basic formulation was later refined to include, when appropriate, corrosion inhibitors, wetting agents, and buffers to control the pH of the solution. Other formulations with higher sterilant concentrations (e.g., 3.4 %) also have been developed.

Several companies now produce glutaraldehyde-based LCSs and HLDs. These products are sometimes referred to as either "acid glutaraldehyde" or "alkaline glutaraldehyde." Products designated as "alkaline" are usually supplied in two parts (active glutaraldehyde solution and activator buffer), which require mixing before use to impart an alkaline pH to the solution (a pH of approximately 8). Those designated as "acid" usually do not require an activator.

Glutaraldehyde-based sterilants usually are used as HLDs for semi-critical devices. Conditions for high-level disinfection generally range from 5-minutes to 90-minutes at 20 ºC to 35 ºC (68 ºF to 95 ºF), depending on the product formulation and glutaraldehyde concentration (Table H.1). For currently available products, the contact time for sterilization is 10-hours at temperatures ranging from 20 ºC to 25 ºC (68 ºF to 77 ºF) or 7-hours and 40-minutes at 35 ºC (95 ºF), depending on the product formulation and glutaraldehyde concentration. Depending on the product, the device sterilization contact conditions indicated in the labeling of a cleared LCS/HLD could be based only on the AOAC Sporicidal Activity Test or on additional simulated-use testing with devices.

Table H.1—Examples of labeled contact conditions for high-level disinfection by FDA-cleared glutaraldehyde products

Glutaraldehyde solution	Contact conditions
12 % glutaraldehyde, 1.93 % phenol–phenate solution	25 ºC (77 ºF), 20-minutes
4 % to 2.6 % glutaraldehyde solution without surfactants	20 ºC to 25 ºC (68 ºF to 77 ºF), 45-minutes
4 % to 2.5 % glutaraldehyde solution with surfactants	20 ºC to 25 ºC (68 ºF to 77 ºF), 45- to 90-minutes
5% glutaraldehyde solution with surfactants	35 ºC (95 F), -minutes
3.0 % to 4.0 % glutaraldehyde solution with surfactants	20 ºC to 25 ºC (68 ºF to 77 ºF), 20- to 90-minutes
4 % glutaraldehyde, 20.1 % isopropanol	20 ºC (68 ºF), 10-minutes

NOTE 1 A complete list of FDA-cleared HLDs and LCSs can be found at the FDA website.

NOTE 2 The 5 % glutaraldehyde solution must be used in an AER with the FDA-cleared capability of maintaining the solution at 35 ºC. Glutaraldehyde-based products can be used in automated or manual high-level disinfection processes. Many automated reprocessors are equipped with temperature-control devices, computerized processing cycles, and bacteria-retentive filters for rinse water, as well as filters for removing suspended materials from the reused disinfectant solution. Although automated reprocessors might control the temperature of the solution in the reservoir, they might not be capable of maintaining the temperature of the solution in the processing chamber during high-level disinfection; the user should check with the manufacturer of the automated reprocessor. It should be noted that formulations containing surfactants might not be suitable for automated systems because of the potential for foaming.

Because the health care industry has used glutaraldehyde for many decades to disinfect and sterilize medical devices, there is a large amount of information in the literature regarding its mechanism of action, the role of pH control, its compatibility with the various materials used to manufacture medical devices, the effect of temperature on the rate of microbial kill, and the procedures that should be used for the safe handling of glutaraldehyde solutions (Alvarado and Reichelderfer, 2000 [68]; Chervenak, 2002 [115], 2003 [116]; Jordan, 1995 [190]; Rubbo, Gardner, and Webb, 1967 [271]; Russell, 1994 [274]; Stonehill, Krop, and Borick, 1963 [304]). Despite this, recent evidence has suggested that some types of microorganisms demonstrate resistance to the antimicrobial effects of glutaraldehyde and might not be inactivated by such disinfectants. Strains of nontuberculous mycobacteria and *Pseudomonas* have shown unique resistance to glutaraldehyde, some of which has been associated with infection outbreaks (Guimarães, 2016 [168]; Neves, 2016 [222]; Fisher, 2012 [149]). Some cyst and even vegetative forms of protozoa also demonstrate resistance to the effects of glutaraldehyde (Barbee et al., 1999 [81]; Coulon et al., 2010 [126]).

The Australian government's 1994 assessment report, *Glutaraldehyde: Priority existing chemical no. 3,* concludes that "glutaraldehyde can be used safely if the proper control measures are in place. The main health effects of glutaraldehyde are irritation of the skin, eyes and respiratory system." For safe and effective use of a product, users should consult the labeling, because the directions vary according to the manufacturer's formulation.

Glutaraldehyde reacts with proteins forming large polymeric molecules by cross-linking (Block, 2001 [94]). On the other hand, small non-toxic amounts of glutaraldehyde remain on the synthetic surfaces of endoscopes after disinfection and rinsing due to its polar properties (Van Drongelen et al., 2006 [366]; Emmrich et al., 2014 [143]). These glutaraldehyde residues react with tissue and body fluids by forming larger molecules and deposits, when the endoscope is used on the next patient. Deposits can be easily identified by means of the white markings on the endoscope after repeatedly manual or automated disinfection with glutaraldehyde. The markings are yellow/brown up to the point where the endoscope is inserted into the patient but continue to be white at other locations (Ofstead et al., 2017 [238] [244] [246]; Biering, 2014 [92]). See Figure H.1. Internal channels of the endoscope, like the biopsy channel, exhibit these yellow/ brown deposits as well (Tucker et al.,1996 [315]).

Figure H.1—Endoscope markings example

Glutaraldehyde is compatible with most device materials used today and can be used to process medical devices containing heat-sensitive materials. Most glutaraldehyde-based chemical sterilants are labeled for reuse for 14- to 28-days. During the recommended reuse period, the concentration of the active ingredients in the solution should be tested with the solution test strips or chemical monitoring devices recommended by the manufacturer, and the testing should be performed according to the label instructions. If the concentration of the active ingredients in the solution falls below the MRC or MEC, the solution should be discarded regardless of how many days it has been in use.

H.1.3 Effective use of glutaraldehyde

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with the selected glutaraldehyde solution.

b) If an automated reprocessor is to be used, the device manufacturer and automated reprocessor manufacturer should be consulted to determine the advisability of using glutaraldehyde products containing a surfactant (which might not be suitable for automated systems because of the potential for foaming).

c) The glutaraldehyde product should be mixed according to the label instructions.

d) Devices should be thoroughly cleaned, the exterior should be dried, and interior channels should be drained or evacuated of all water before they are immersed in the HLD solution to avoid adding debris to the solution or diluting the solution, both of which can shorten the duration of efficacy.

e) Devices should be thoroughly and completely immersed in the HLD solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with the HLD, as recommended.

f) A solution test strip or chemical monitoring device should be used to test the concentration of the active ingredients before each use. Only those solution test strips, or chemical monitoring devices recommended by the glutaraldehyde product manufacturer should be used. Quality control checks of the solution test strips, or chemical monitoring devices should be performed according to the manufacturer's written IFU.

g) When the concentration of the active ingredients falls below the MRC or MEC, the solution should no longer be used.

h) Solutions should be kept covered to prevent evaporation.

i) Solutions that evaporate or drain below the soak level might require additional solution to facilitate complete immersion of the device. Before adding solution, the user must first consult the HLD manufacturer's IFU to

ensure that the manufacturer permits the adding of solution. The solution cannot be used beyond the original soaking solution expiration date (use life). Before being used, the solution must be tested for MEC or MRC.

j) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. A glutaraldehyde product might be labeled for 14-day use, for 28-day use, or (if it is a concentrate) for one-time use.

k) Any deviations from the label instructions for contact time should be documented; the documentation should include a rationale.

l) Glutaraldehyde solutions should not be used beyond their shelf life.

m) Unopened solutions should be stored in a cool, well ventilated area at the temperature recommended by the manufacturer.

H.1.3.1 Safe use of glutaraldehyde

H.1.3.1.1 General considerations for occupational exposure

Procedures should be developed that will prevent contact with glutaraldehyde solution and reduce exposure to glutaraldehyde vapor to the lowest reasonably obtainable level below the ACGIH® TLV®-C (Ceiling Threshold Limit Value). Personnel should always wear appropriate PPE when using glutaraldehyde solutions (see 6.6.2 and H.1.3.2.3).

Rationale: Exposure to glutaraldehyde vapor, even at levels below the ACGIH® TLV®-C, can cause symptoms such as headaches and irritation of eyes, nose, and throat. These symptoms should disappear when the individual leaves the area of glutaraldehyde use. Exposure to glutaraldehyde vapor can also cause asthma-like symptoms in some individuals.

H.1.3.2 Health effects of glutaraldehyde

H.1.3.2.1 Potential health effects of short-term exposure

Glutaraldehyde is an irritant to the skin, eyes, gastrointestinal tract, and respiratory system.

Skin contact can cause minor irritation with itching and slight local redness. Prolonged skin contact causes mild to moderate local redness and swelling. Even in low concentrations, there is a potential for liquid glutaraldehyde to be a contact sensitizer, through the dermal route of exposure, in a small percentage of exposed individuals. Glutaraldehyde in concentrations of less than 10 % is not known to be absorbed through the skin in harmful amounts. Glutaraldehyde is a protein cross-linking agent, and its reactivity with skin proteins is a major factor in limiting percutaneous absorption.

Glutaraldehyde in concentrations of more than 0.1 % is irritating to the eyes. Eye contact causes moderate to severe irritation, experienced as discomfort or pain, excessive blinking, and tear production, with marked redness and swelling of the conjunctiva. Ocular contact with aqueous solutions containing 2 % or higher concentrations of glutaraldehyde can cause severe eye irritation and damage, including minor to moderate corneal injury that can persist and, if not adequately and promptly treated, result in permanent impairment of vision.

If swallowed, glutaraldehyde in concentrations of less than 5 % can be mildly to moderately irritating to the mouth, throat, and stomach. There could be abdominal discomfort or pain, nausea, vomiting, diarrhea, dizziness, and weakness. Nose and throat irritation and general tightness of the chest have been reported by workers exposed to glutaraldehyde vapor.

Vapors generated from glutaraldehyde can be irritating to the respiratory tract, and current information suggests that inhalation of the vapor can cause asthma-like symptoms as well as aggravate pre-existing asthma and inflammatory or fibrotic pulmonary disease. Nosebleeds have also been reported in workers exposed to glutaraldehyde but are rare. For these reasons, all glutaraldehyde solutions should be used in well ventilated areas or in free-standing or vented chemical fume hoods. These symptoms are generally temporary and should subside when the individual leaves the area of glutaraldehyde exposure.

Evidence indicates that skin and respiratory irritant effects are exacerbated on repeated exposure to glutaraldehyde. The information in this section is based on Ballantyne (1995) [75], Ballantyne and Jordan (2001) [76], and—in the case of the information on skin effects of prolonged contact with glutaraldehyde—Fowler (1989) [151]. Reports describing asthma-like symptoms resulting from overexposure to high vapor concentrations have been published. It is unknown whether these symptoms are associated with an immune-mediated mechanism or are provoked by irritating concentrations, because the current body of evidence is inconclusive.

H.1.3.2.2 Potential health effects of long-term exposure

Respiratory irritation and skin-sensitizing effects of glutaraldehyde have been confirmed (Beauchamp et al., 1992 [85]). There is no evidence that exposure to glutaraldehyde causes adverse reproductive health effects, and a mortality study did not reveal an increased incidence of cancer deaths. Animal studies have shown no evidence of any target organ toxicity. Case reports have suggested an association between glutaraldehyde and asthma-like symptoms (Chan-Yeung et al., 1993 [112]; Stenton et al., 1994 [303]; Gannon et al., 1995 [159]; Di Stefano et al., 1999 [132]). To date, only a very small number of cases have been diagnosed as asthma based on both clinical features and appropriate investigational procedures.

Glutaraldehyde is listed as a Group 3 carcinogen (“unclassifiable as to carcinogenicity to humans”) by the International Agency for Research on Cancer (IARC) and as “not classifiable as a human carcinogen” by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) [179]. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2022 [70].

H.1.3.2.2.1 Occupational exposure limits

Ceiling threshold limit values for glutaraldehyde should be measured and documented on a schedule that is consistent with facility policy and procedures. Currently, ACGIH® recommends a TLV®-C for glutaraldehyde of 0.05 parts per million volume (ppmv) (ACGIH®, 2022) [70]. A threshold limit value is the airborne concentration of a substance to which "it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be affected more seriously by aggravation of a pre-existing condition, or by development of an occupational illness” (ACGIH®, 2022) [70]. However, federal OSHA can enforce exposure limits, including the currently ACGIH®-recommended TLV®-C for glutaraldehyde, by means of its General Duty Clause, which is designed to ensure that each employer provides a workplace for employees that is free from recognized hazards. Additionally, states with federally approved state OSHA programs can opt to enforce exposure limits as originally promulgated in the Air Contaminants Standard or their own stricter standards.

NOTE The occupational exposure limits discussed above were current at the time this document was published. However, it is essential that health care personnel keep informed of the status of federal, state, and local regulations applicable to glutaraldehyde, as well as with professional guidelines published by such organizations as ACGIH®. Certain EPA regulations also apply to glutaraldehyde. Users should contact the federal EPA office or their state EPA offices for information on EPA requirements. Additional regulatory information can be obtained from the manufacturer’s SDS.

H.1.3.2.3 Personal protective equipment and first aid

H.1.3.2.3.1 Eye protection

Splashproof goggles or both safety glasses with side shields and a wraparound full-face shield should always be worn when working around glutaraldehyde-based LCSs/HLDs. For eye protection, both safety glasses and face shields are needed, because many face shields alone do not offer total protection against eye contamination, and their use should be considered an adjunct to safety glasses to protect facial skin. If any eye contact should occur, the eye should be washed immediately and continuously with flowing water for at least 30-minutes. (Flushing with water dilutes and removes the glutaraldehyde.) Contact lenses should be removed after the first 5-minutes and the washing continued. The employee should then receive prompt medical attention, preferably from an ophthalmologist.

H.1.3.2.3.2 Skin protection

For glutaraldehyde, nitrile and butyl rubber are the most impervious materials; gloves made of polyethylene and certain man-made copolymers give protection for several hours (Jordan, et al., 1996 [191]). The permeability of gloves varies considerably, depending on the manufacturer; therefore, the recommendations of the glove manufacturer and the LCS/HLD manufacturer should be consulted. Polyvinyl chloride and neoprene gloves do not give adequate protection from glutaraldehyde and can absorb the chemical; therefore, the use of these types of gloves is not recommended. The use of latex gloves also is not recommended, because they are not designed to protect against chemical exposures. Permeation and degradation periods should be considered when selecting gloves for specific activities and use with chemicals.

Personnel who have come into contact with liquid glutaraldehyde should immediately remove contaminated clothing and shoes and thoroughly wash contaminated skin with flowing water for 15- to 20-minutes. Exposed personnel should receive prompt medical attention from a physician—ideally an occupational health physician—immediately after these emergency measures. Contaminated reusable clothing should be laundered before it is worn again, and rubber goods should be rinsed thoroughly before use. Any heavily contaminated clothing, shoes, or equipment that cannot be thoroughly washed and decontaminated should be discarded.

NOTE 1 Information on current OSHA regulations can be obtained at OSHA's website, http://www.osha.gov. Information on current ACGIH® guidelines can be obtained at ACGIH's website, http://www.acgih.org, or by contacting the American Conference of Governmental Industrial Hygienists, Technical Affairs Office, Kemper Woods Center, 1330 Kemper Meadow Drive, Cincinnati, OH 45240, (513) 742-2020, fax (513) 742-3355.

NOTE 2 Information on current EPA regulations can be obtained at EPA's website, http://www.epa.gov, or by contacting the U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 272-0167.

H.1.3.2.3.3 Respiratory protection

See 4.4.4 of ANSI/AAMI ST58:2013/(R)2018 [14].

H.1.3.3 Ventilation

Glutaraldehyde solutions should be prepared and used in a well ventilated area or in freestanding or vented chemical fume hoods (see H.1.3.1).

H.1.3.4 Preparing activated solutions

Glutaraldehyde solutions should be prepared and activated according to the manufacturer's written IFU. Appropriate PPE should be worn (see 6.6.2), and every effort should be made to minimize splashing, spilling, and personnel exposure. Preparation of activated solutions should be performed only in a properly ventilated area. The date of activation (mixing date) and the expiration date should be recorded on the activated solution container and documented according to facility policies and procedures.

Rationale: The recommended ventilation, spill prevention procedures, and appropriate PPE are intended to protect the worker from the irritating and sensitizing effects of glutaraldehyde. The activation and expiration dates should be recorded to ensure that the solution will not be used longer than its effective use life.

H.1.3.5 Pouring activated solutions

The solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the chemical solution and reduce exposure to glutaraldehyde vapor to the lowest reasonably obtainable level below the TLV®-C. Agitation and splashing during transfer should be minimized. Examples of methods of minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with glutaraldehyde-based products prevents skin and eye injury and minimizes the potential for skin sensitization, which has been reported in a small proportion of users. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also H.1.3.2.

H.1.3.6 Transporting solutions

Transport of glutaraldehyde solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport an activated solution to another area, that area should be properly ventilated, and a transport method should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area of the solution and thus increase the potential for vapor to raise the air concentration above the TLV®-C. Spills also increase the potential for skin and eye contact and irritation.

H.1.3.7 Storing activated and unused solutions

Glutaraldehyde should be stored in a closed container or system in a well ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5]) [230], with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of glutaraldehyde vapor and liquid.

Rationale: A closed system will minimize evaporation of the glutaraldehyde and subsequent personnel exposure to vapor.

H.1.3.8 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing instruments or other items into the activated solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the activated solution, taking care to disturb and agitate the surface of the solution as little as possible.

NOTE Ensure that there are no air bubbles remaining on the surface of the device during the exposure time. When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The instruments or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve high-level disinfection or sterilization. (See the device manufacturer's written IFU for additional recommendations on high-level infection and sterilization.)

Rationale: These procedures will help prevent worker exposure to glutaraldehyde and help ensure the effectiveness of the high-level disinfection or sterilization process. Reusing syringes for irrigation or flushing could lead to contamination of the solution.

H.1.3.9 Rinsing high-level-disinfected or sterilized items

Personnel should wear appropriate PPE when removing items from the activated solution; this activity should take place in a properly ventilated area. Before removing the device from the solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening.

The instruments should be gently removed from the solution and rinsed thoroughly in clean, utility water or (if the items are to be used in a sterile field) sterile water. (Personnel should don a new pair of gloves and then replace the cover on the solution container.) To remove all residual solution, personnel should rinse the external surfaces of the items

and any removable parts with copious amounts of clean running water; should immerse them in successive containers of clean water (the rinse solution should be discarded after each use, not reused); or should otherwise rinse the device in accordance with the manufacturer's written IFU. For instruments with interior channels, each channel or the all-channel irrigator should be flushed several times with clean water until all residual solution is removed from the channels (at least 500 milliliters [mL] of water during each separate rinse, unless the device manufacturer instructs otherwise). The flushing procedure should be repeated with air. For instruments with interior channels, the channels should be flushed with 70 % to 90 % ethyl or isopropyl alcohol, followed by forced air, to facilitate drying. (However, see the device manufacturer's written IFU.)

Additional care should be taken to ensure that the recommended number of freshwater rinses are performed to ensure that residual levels of glutaraldehyde are removed, due to toxicity concerns. The external surfaces of instruments should be thoroughly wiped dry with a sterile, non-linting cloth.

Rationale: Proper procedures for rinsing, flushing, drying, and storing instruments will help prevent worker exposure to glutaraldehyde and help ensure that residual glutaraldehyde is not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution and to prevent the retention of solution that could occur in standing water (Durante, et al., 1992 [141]). The flushing of channels with alcohol followed by air greatly reduces the possibility of recontamination of instruments by waterborne microorganisms. See also ASGE [54] and SHEA (2011) [105].

H.1.4 Procedures for cleaning up glutaraldehyde spills

NOTE Glutaraldehyde spills need not be reported to regulatory authorities responsible for air quality (e.g., state health or environmental authorities such as a state Air Control Board, OSHA, or EPA). Glutaraldehyde does not have a reportable quantity(RQ) established by EPA under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA), nor is it on the toxic release inventory (TRI) list established under the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title III. Glutaraldehyde concentrations of 1 % or more are listed in some states' right-to-know regulations. Because glutaraldehyde contains no levels of listed substances that California has found to cause cancer, birth defects, or other reproductive harm, it is not listed under Proposition 65.

H.1.4.1 General considerations

All spills, no matter how small, should be cleaned up immediately. The glutaraldehyde concentration, the volume of the spill, the temperature of the room and the solution, and the type of ventilation in the area of the spill will affect whether it can be cleaned up safely without the use of inactivating chemicals and respiratory equipment. It is safer not to use a volume measurement to differentiate between a drip, a splash, a small spill, and a large spill but instead to provide recommendations based on the assumption that anything larger than a drip or splash might need to be inactivated. Personnel might need to wear respirators, depending on the volume of the spill and the area ventilation. Use of a respirator is required for any spill with unknown vapor concentrations.

H.1.4.2 Deactivating chemicals

Several chemicals can be used to reduce the glutaraldehyde concentration in solutions and reduce ambient vapor levels in spill situations; there are also a number of commercially available products designed for this purpose. Such chemicals have varying degrees of activity; some are used to deal with the solution, some with vapor. Before using a glutaraldehyde-based product, health care personnel should be familiar with the manufacturer's specific written recommendations and supporting technical data for chemicals to be used to clean up spills.

H.1.4.3 Drips and splashes

It is important that all spills, including drips and splashes, be cleaned up immediately. All necessary cleanup equipment, including a mop and bucket, plastic dustpans, plastic trash bags, and sponges and towels, should be readily available. All appropriate PPE should be worn (see 6.6.2 and H.1.3.2.3).

Drips and splashes can be wiped up quickly with a sponge, towel, or mop. Alternatively, the glutaraldehyde solution can be neutralized with an appropriate chemical agent (see H.1.4.2) and then wiped up with a sponge, towel, or mop. The sponge, towel, or mop should be thoroughly rinsed with large amounts of water, and the water should be discarded down the drain. After being rinsed, reusable sponges, towels, or mop heads should be placed in the appropriate

container to be laundered before reuse. After being rinsed, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: The most important thing is to clean up the glutaraldehyde solution quickly to control vapor and prevent contact with skin or eyes. For small drips and splashes, it is not necessary to neutralize the glutaraldehyde, because the amount being rinsed down the drain will not exceed 5 ppm by the time it reaches a sewage treatment plant, nor is it likely to cause the room vapor to exceed the TLV®-C. However, there is no harm in neutralizing the glutaraldehyde, regardless of the amount.

H.1.4.4 Large spills

Any glutaraldehyde spill larger than a small drip or splash can cause vapor levels to increase above the TLV®-C. The spill should be cleaned up by a team equipped with the appropriate respiratory equipment for the ambient air concentration of glutaraldehyde vapor (see H.4.4); the appropriate PPE (including rubber boots or shoe protection); and the necessary cleanup tools: mop, sponges, towels, squeegee, plastic dustpan, plastic scoop, and a chemical for deactivating the glutaraldehyde (see H.1.4.2).

Large spills should be contained and neutralized or contained and collected for disposal. When spills are contained, it might be possible to neutralize the spilled solution with an appropriate chemical agent (see H.1.4.2). Depending on the amount of solution and the environmental conditions, some heat and fumes could be liberated by the reaction. When large spills are collected using an absorbent, the absorbed medium can be disposed of or incinerated according to appropriate federal, state, and local regulations.

After the glutaraldehyde solution is collected and disposed of, the area where the glutaraldehyde solution was collected should be thoroughly rinsed. The cleanup tools should be rinsed with large amounts of water, and the water should be discarded down the drain. Reusable cleanup tools, such as sponges, towels, or mop heads, should be placed in an appropriate container to be laundered before reuse. After being rinsed, disposable sponges, towels, or mop heads should be disposed of according to the procedures designated by the glutaraldehyde spill containment response team.

Rationale: Immediate neutralization and cleanup of spills minimizes the potential for chemical exposure. Spills increase the surface area of the glutaraldehyde solution and, if left unattended, will increase the air concentration of glutaraldehyde. Larger spills present increased risk because the TLV®-C could be exceeded; also, additional considerations are necessary for disposal of contaminated equipment and the neutralized solution. Proper respirators, appropriate PPE, and training are essential to preventing overexposure of workers and others in the area (see also H.1.3.2.3).

H.1.5 Disposal of glutaraldehyde solutions

Five-day biological demand and aquatic metabolism studies indicate that glutaraldehyde degrades readily. Also, glutaraldehyde does not inhibit the growth of unacclimated sewage microorganisms at concentrations less than 5 milligrams/liter (mg/L) or 5 ppm.

Regulations for disposal of chemicals into the public sewer system vary with location. Check with your local public wastewater authority for applicable regulations. Because glutaraldehyde is diluted by other waste streams in a municipal sewage system and because it is deactivated by proteinaceous components of sewage effluent, some authorities have concluded that the disposal of spent glutaraldehyde will have no adverse effects on the sewage treatment plant. Solution containers should be rinsed according to label directions before being discarded.

NOTE Bio-oxidation studies were conducted by Union Carbide Corporation according to APHA (1976) [26]. For additional information, see Dow Chemical Company (2003) [137].

NOTE The Australian Government's 1994 Assessment Report, Glutaraldehyde: Priority existing chemical no. 3, estimated "that concentrations of glutaraldehyde in sewage treatment plants will remain below 200 mg/L." Such levels do not constitute a significant environmental hazard and will be reduced further by biodegradation during sewage treatment."

H.2 Hydrogen peroxide solutions

H.2.1 Introduction

Hydrogen peroxide-based solution products have been cleared by the FDA for use as HLDs and LCSs used primarily for heat-sensitive medical devices (e.g., flexible endoscopes). This section covers the properties and applications of hydrogen peroxide solutions; the occupational exposure considerations specific to hydrogen peroxide, including vapor monitoring and procedures for handling spills; and the disposal of hydrogen peroxide solutions.

H.2.2 Properties and applications of hydrogen peroxide

Hydrogen peroxide-based solution products are generally used as HLDs for heat-sensitive and submersible medical devices such as flexible or rigid endoscopes. Hydrogen peroxide products do not require activation, being formulated as ready-to-use liquid chemical germicides. They are generally odorless, reusable, and can be used in manual soak applications or automated endoscope processing systems.

One product contains 2 % hydrogen peroxide, buffers, chelating agents, and a corrosion inhibitor. The labeled contact conditions are 8-minutes at 20 ºC (68 ºF). The product has a reuse life of 21-days at or above its MRC/MEC of 1.5 % hydrogen peroxide.

A second product contains 7.5 % hydrogen peroxide, 0.85 % phosphoric acid, and 91.65 % inert ingredients. The labeled contact conditions for HLD are 30-minutes at 20 ºC (68 ºF); for sterilization, the labeled contact conditions are 6 hours at 20 ºC (68 ºF). The product has a reuse life of 21 days at or above its MRC/MEC of 6 % hydrogen peroxide.

Before each processing cycle, both products should be checked to verify that the concentration of the active ingredient (hydrogen peroxide) is at or above the MRC/MEC with the appropriate solution test strips or chemical monitoring devices recommended by the manufacturer. This hydrogen peroxide product might cause cosmetic damage (e.g., discoloration) to a device. As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

H.2.3 Effective use of hydrogen peroxide solutions

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with hydrogen peroxide. If the IFU does not specifically reference hydrogen peroxide, it is recommended that before using the solution, users should consult with the device manufacturer to ensure device compatibility.

b) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with the specific hydrogen peroxide product.

c) Devices should be disassembled and thoroughly cleaned and dried before they are immersed in the solution in order to avoid adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

d) A solution test strip or chemical monitoring device should be used to test the concentration of the solution before each processing cycle. Only those solution test strips, or chemical monitoring devices recommended by the hydrogen peroxide product manufacturer should be used. Quality control checks of the solution test strips, or chemical monitoring devices should be performed according to the manufacturer's written IFU.

e) Devices should be thoroughly and completely immersed in the hydrogen peroxide solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with hydrogen peroxide, as recommended.

f) When the concentration of hydrogen peroxide falls below the MRC/MEC, the solution should no longer be used.

g) Solutions should be kept covered to prevent evaporation.

h) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded, and a fresh solution prepared.

i) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of hydrogen peroxide is at or above the MRC/MEC.

j) Solutions should not be used beyond their shelf life. Manufacturer's written IFU should be consulted to determine the unopened-container and opened-container shelf life of the product.

k) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

H.2.4 Safe use of hydrogen peroxide solutions

H.2.4.1 Occupational exposure

H.2.4.1.1 General considerations

Procedures should be developed that will prevent contact with hydrogen peroxide solution and reduce exposure to hydrogen peroxide vapor to the lowest reasonably obtainable level below the OSHA PEL of 1 ppm.

Care should be taken to avoid contact with the hydrogen peroxide solution. Concentrations of hydrogen peroxide above 6 % can cause bleaching of the skin and in some cases chemical burns. When using hydrogen peroxide solutions, users must wear appropriate PPE, including gloves and eye protection (e.g., splash goggles). Hydrogen peroxide solutions should only be used in well ventilated areas, preferably with local exhaust to remove vapors. If any contact with the skin should occur, the area should be washed with large amount of water. If the hydrogen peroxide solution contacts the eyes, flush the eyes immediately with water in an eye wash station and then seek medical attention.

Personnel should always wear appropriate PPE when using hydrogen peroxide solutions (see H.2.4.1.4).

H.2.4.1.2 Health effects of hydrogen peroxide

H.2.4.1.2.1 Potential health effects of short-term exposure

The manufacturer’s SDS should be consulted regarding potential health effects from exposure to hydrogen peroxide. The effects of exposure can vary from product to product and manufacturer to manufacturer.

The 7.5 % hydrogen peroxide solution is severely irritating and corrosive to the eyes, skin, and gastrointestinal tract. Excessive exposure could cause irreversible tissue damage to the eyes, including blindness. Inhalation of vapors can be severely irritating to the nose, throat, and lungs.

The 2 % hydrogen peroxide solution is a mild irritant to the eyes and a slight irritant to the skin. Any tissues that come in contact with the 2 % hydrogen peroxide solution should be rinsed immediately. Inhalation of hydrogen peroxide vapors can be irritating to the nose, throat, and lungs.

H.2.4.1.2.2 Potential health effects of long-term exposure

IARC, NTP, and OSHA do not list hydrogen peroxide as a carcinogen. ACGIH® lists hydrogen peroxide as an A3 animal carcinogen.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) [179]. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2022) [70].

H.2.4.1.3 Occupational exposure limits

The OSHA PEL for hydrogen peroxide vapor is 1 ppm as an 8-hour TWA.

H.2.4.1.4 Personal protective equipment and first aid

H.2.4.1.4.1 Eye protection

For the 2 % hydrogen peroxide solution, safety glasses or goggles should be worn. For the 7.5 % hydrogen peroxide solution, cup-type chemical goggles, a full-face shield, or both should be worn. If any eye contact should occur, the eye should be flushed immediately with plenty of water for at least 15-minutes. Medical advice should be sought.

H.2.4.1.4.2 Skin protection

Rubber, neoprene, vinyl, or nitrile gloves should be worn to protect hands. Other appropriate protective clothing, including long sleeves, should be worn to minimize exposure to the skin. If any skin contact should occur, the affected area of the skin should be thoroughly washed and rinsed according to the manufacturer's written IFU and the SDS.

H.2.4.1.4.3 Respiratory protection

See 4.4.4 of ANSI/AAMI ST58:2013/(R)2018 [14].

H.2.4.2 Ventilation

Hydrogen peroxide solutions should be used in a well-ventilated area (see H.2).

H.2.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the chemical solution and reduce exposure to hydrogen peroxide to the lowest reasonably obtainable level below the OSHA PEL. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor, where necessary, include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with hydrogen peroxide products prevents skin and eye injury. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also H.2.4.1.2.

H.2.4.4 Transporting solutions

Transport of hydrogen peroxide solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration above the TLV®. Spills also increase the potential for skin and eye contact and irritation, as described in H.2.4.1.2.

H.2.4.5 Storing unused solutions

Hydrogen peroxide solutions should be stored in vented, closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5][i]) [230], with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution.

Automated systems should be designed to prevent the escape of hydrogen peroxide vapor and liquid.

Rationale: A closed system will minimize evaporation of the hydrogen peroxide solution and subsequent personal exposure to vapor.

H.2.4.6 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing instruments or other items into the solution; this activity should take place in a properly ventilated area. Personnel should gently place clean, dry items into the solution, taking care to minimize splashing. When the solution must be manually irrigated or flushed through internal channels or lumens of an instrument, personnel should take care to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The instruments or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve HLD or sterilization. (See the device manufacturer's written IFU for additional recommendations on HLD and sterilization.)

Rationale: These procedures will help prevent worker exposure to hydrogen peroxide and help ensure the effectiveness of the HLD or sterilization process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

H.2.4.7 Rinsing disinfected or sterilized items

Personnel should wear appropriate PPE when removing items from the solution; this activity should take place in a properly ventilated area. Before removing the device from the solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution. The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening. The instruments should be gently removed from the solution and rinsed thoroughly in clean, utility water or (if the items are to be used in a sterile field) sterile water. Personnel should rinse their gloved hands with water and then replace the cover on the solution container. The product-specific rinsing instructions should be followed to ensure that all external surfaces of the items and any removable parts are free of all residual solution.

The rinse solution should be discarded after each use. For instruments with interior channels, each channel or the all-channel irrigator should be flushed according to the manufacturer's written IFU with clean water until all residual solution is removed from the channels. The flushing procedure should be repeated with air. For instruments with interior channels, the channels may be flushed with 70 % to 90 % ethyl or isopropyl alcohol, followed by forced air, to facilitate drying. Check the device manufacturer's written IFU regarding device internal channel compatibility with alcohol. The external surfaces of instruments should be thoroughly wiped dry with a sterile, non-linting cloth.

Rationale: Proper procedures for rinsing, flushing, drying, and storing instruments will help prevent worker exposure to hydrogen peroxide and help ensure that residual hydrogen peroxide is not introduced into patient tissue. Complete immersion in water ensures that all external surfaces of the device come into contact with the rinse water.

H.2.5 Hydrogen peroxide spills

Spilled hydrogen peroxide solutions should be collected, confined, and diluted to a safe concentration, or absorbed into inert media and disposed of appropriately. The best method will depend on the size of the spill and concentration of the hydrogen peroxide and should be included in the facility’s safety plan.

H.2.6 Disposal of hydrogen peroxide solutions

Hydrogen peroxide solutions should be diluted with a large amount of water, and the hydrogen peroxide should be allowed to decompose. Higher concentrations of hydrogen peroxide should be allowed to decompose. The diluted solution may then be discharged into a suitable treatment system in accordance with federal, state, and local regulations. Solution containers should be rinsed according to label directions before being discarded.

H.2.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

H.3 Ortho-phthalaldehyde solutions

H.3.1 Introduction

Ortho-phthalaldehyde (OPA) based products have been cleared by the FDA for use as an HLD for processing heat sensitive medical devices. This section covers the properties and applications of OPA; occupational exposure considerations specific to OPA, including vapor monitoring and procedures for handling spills; and the disposal of OPA.

H.3.2 Properties and applications of OPA

Ortho-phthalaldehyde solution is an HLD intended for use in processing heat-sensitive devices. It is particularly active against certain strains of mycobacteria, but some strains show high-level resistance to OPA (Svetlikova, et al., 2009 [306]; McDonnell, 2007 [210]). Some cyst and even vegetative forms of protozoa also demonstrate resistance to OPA (Barbee, et al., 1999 [81]; Coulon, et al., 2010 [126]). Ortho-phthalaldehyde solutions do not require activation. These solutions have no odor to mild odor. Several OPA products contain 0.55 % to 0.60 % OPA, corrosion inhibitors, chelating agents, and a dye in phosphate buffer. They have been cleared for use as an HLD for manual processing (12-minutes at 20 ºC [68 ºF]) and for processing in automated endoscope reprocessors (5-minutes at 25 ºC [77 ºF]) that have FDA-cleared capability to maintain solution temperature at 25 ºC (77 ºF). If the solution temperature cannot be maintained at 25 ºC (77 ºF) in an AER, the device should be processed using the parameters for manual processing. In both applications, the products have a reuse life of 14-days.

Another OPA formulation is designed for single use in an automated system. In this system, concentrated (5.75 %) OPA is diluted with buffers, chelating agents, corrosion inhibitors, and a dye to its 0.05 % “in-use” solution. The labeled contact conditions for HLD are 10-minutes at 50 ºC to 55 ºC (122 ºF to 131 ºF). Although OPA products—and all FDA-cleared HLDs—must pass the AOAC Sporicidal Test (Horwitz and Latimer, 2010 [175]), there is no sterilization claim for them.

Ortho-phthalaldehyde solution should not be used to process any urological instrumentation used to treat patients with a history of bladder cancer. In rare instances, OPA solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies (Joshi and Rosenfeld, 2004 [193]; Sokol, 2004a [298], 2004b [299]). As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

For additional information on OPA as a HLD, see Alfa and Sitter (1994) [53], Rutala and Weber (2001) [276], Gregory, et al. (1999) [167], and Walsh, et al. (1999) [370].

H.3.3 Effective use of OPA

To ensure efficacy, the user should observe the following guidelines:

a) The medical device manufacturer’s written IFU should be consulted to determine and provide in writing the compatibility of the device with the selected OPA solution.

b) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with OPA solution.

c) Blood, other body fluids, and lubricants must be thoroughly cleaned from the surfaces and lumens of medical devices before the devices are processed in the disinfectant. Blood and other body fluids should be disposed of according to all applicable regulations for infectious waste disposal. The medical device manufacturer’s written IFU for device disassembly, decontamination, and leak testing should be followed.

d) All surfaces and lumens of cleaned devices should be thoroughly rinsed and rough-dried.

e) The date that the OPA container was opened should be recorded on the container label and documented. After the container is opened, the solution remaining in the container may be stored for up to 75-days until used (provided that the 75-days does not extend past the expiration date on the container).

f) The reusable solution in the secondary container can be used for a period of up to 14-days. The solution should be discarded after 14-days even if the OPA solution test strip or chemical monitoring device indicates a concentration at or above the MRC or MEC.

g) The device should be completely immersed in the OPA solution, filling all lumens, and eliminating air pockets, for at least 12-minutes at a minimum temperature of 20 ºC (68 ºF).

h) A solution test strip or chemical monitoring device should be used to test the concentration of OPA before each processing cycle. Only those solution test strips, or chemical monitoring devices recommended by the OPA product manufacturer should be used. Quality control checks of the tests strips or chemical monitoring devices should be performed according to the manufacturer's written IFU.

i) Solutions should be kept covered to prevent evaporation.

j) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded, and a fresh solution prepared.

k) Ortho-phthalaldehyde solutions should not be used beyond their shelf life.

l) Unopened solutions should be stored in a cool, well-ventilated area at the temperature recommended by the manufacturer.

H.3.4 Safe use of OPA

H.3.4.1 Occupational exposure

H.3.4.1.1 General considerations

Procedures should be developed that will prevent contact with OPA solutions. Personnel should always wear appropriate PPE, including gloves, long sleeves, and splash proof monogoggles, when using OPA solutions (see H.3.4.1.4).

H.3.4.1.2 Health effects of OPA

H.3.4.1.2.1 Potential health effects of short-term exposure

Breathing OPA vapors may be irritating to the nose, throat, or respiratory system and may cause coughing, chest discomfort and tightness, difficulty with breathing, or headache. Preexisting bronchitis or asthma conditions can be aggravated by exposure to OPA solutions, as can skin conditions such as dermatitis. Ocular contact with diluted solutions of OPA can cause eye irritation and damage. OPA can also stain skin and, if processed instruments are not rinsed properly, patient tissue. At use concentrations, OPA can be a contact sensitizer through the dermal route of exposure. OPA is a potent sensitizer that, in susceptible individuals, might induce anaphylaxis (Joshi and Rosenfeld, 2004 [193]; Sokol, 2004a [298], 2004b [299]).

H.3.4.1.2.2 Potential health effects of long-term exposure

Neither IARC nor ACGIH® has established carcinogen classifications for OPA.

H.3.4.1.3 Occupational exposure limits

Currently, there is no OSHA PEL for OPA, nor is there an ACGIH®-recommended TLV®.

H.3.4.1.4 Personal protective equipment and first aid

H.3.4.1.4.1 Eye protection

Splashproof monogoggles should be worn. If any eye contact should occur, the eye should be rinsed immediately with plenty of water for at least 15-minutes. Medical advice should be sought.

H.3.4.1.4.2 Skin protection

Polyvinylchloride and nitrile or butyl rubber gloves are suitable for routine use. The permeability of gloves varies considerably, depending on the manufacturer; therefore, the written recommendations of the glove manufacturer and the LCS/HLD manufacturer should be consulted. If any skin contact should occur, the affected area should be washed immediately with soap and water and rinsed for at least 15-minutes. If a skin reaction occurs, medical advice should be sought.

H.3.4.1.4.3 Respiratory protection

See 4.4.4 of ANSI/AAMI ST58:2013/(R)2018 [14].

H.3.4.2 Ventilation

Solutions containing OPA should be used in a well-ventilated area (see H.3.4).

H.3.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry disinfection container by a method that will prevent personnel contact with the chemical solution and reduce exposure to OPA. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with OPA prevents skin and eye injury and protects the worker from the sensitizing effects of OPA. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. Avoiding contact with OPA solution prevents staining of the skin. See also H.3.4.1.2.1.

H.3.4.4 Transporting solutions

Transport of OPA solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected (e.g., empty secondary container along with the bottle of OPA) that will minimize the potential for spills and the possibility of personnel exposure to the solution or vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration of OPA. Spills also increase the potential for skin and eye contact and irritation, as described in H.3.4.1.2.1.

H.3.4.5 Storing opened solutions

Solutions containing OPA should be stored in closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5] [230]), with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; containers should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of OPA vapor and liquid.

Rationale: A closed system will minimize evaporation of OPA and subsequent personnel exposure to vapor.

H.3.4.6 Immersing items to be high-level disinfected

Personnel should wear appropriate PPE when placing instruments or other items into the solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the solution, taking care to disturb and agitate the surface of the solution as little as possible.

When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The instruments or other items should be allowed to soak for the amount of time and at the temperature specified by the manufacturer to achieve disinfection. (See the device manufacturer's written IFU for additional recommendations on disinfection.)

Rationale: These procedures will help prevent worker exposure to OPA and help ensure the effectiveness of the disinfection process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

H.3.4.7 Rinsing disinfected items

Personnel should wear appropriate PPE when removing items from the solution; this activity should take place in a properly ventilated area. Before removing the device from the disinfecting solution, personnel should remove the solution from the internal channels or lumens of the device by flushing each channel several times with a syringe filled with air. Personnel should be careful to avoid being splashed with the solution.

The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening. The instruments should be gently removed from the solution and rinsed thoroughly in clean, utility water or (if the items are to be used in a sterile field) sterile water. (Workers should rinse their gloved hands with water and then replace the cover on the solution container.)

To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of clean running water; should immerse them in successive containers of clean water (the rinse solution should be discarded after each use, not reused); or should otherwise rinse the device in accordance with the manufacturer's written IFU. For instruments with interior channels, each channel or the all-channel irrigator should be flushed several times with clean water until all residual solution is removed from the channels (at least 500 mL of water during each separate rinse, unless the instrument manufacturer instructs otherwise). The flushing procedure should be repeated with air. To facilitate drying of instruments with interior channels, the channels can be flushed with 70 % to 90 % ethyl or isopropyl alcohol, followed by forced air. See the device manufacturer's written IFU for specific instructions. Additional care should be taken to ensure that the recommended number of freshwater rinses are performed to ensure that residual levels of OPA are removed, due to toxicity concerns. The external surfaces of instruments should be thoroughly wiped dry with a sterile, non-linting cloth.

Rationale: Proper procedures for rinsing, flushing, drying, and storing instruments will help prevent worker exposure to OPA and help ensure that residual OPA is not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution, to prevent the retention of solution that could occur in standing water (Durante, et al., 1992 [362]), and to prevent staining of patient tissue.

H.3.5 OPA spills

Personnel responsible for cleanup of OPA spills should have demonstrated competency in hazardous material spill cleanup procedures and should wear appropriate PPE, which should include at least:

a) splash proof monogoggles;

b) polyvinylchloride, nitrile, or butyl rubber gloves;

c) rubber boots or other shoe protection; and

d) for spills larger than one gallon, an OSHA/NIOSH-approved reusable or disposable breathing mask equipped with an organic vapor cartridge filter.

For spill neutralization, there are several commercial products available to neutralize OPA. Alternatively, the following procedure should be followed:

1) The spilled liquid should be collected with sponges, mopped into a plastic container suitable for the size of the spill, or both.

2) Approximately 25 grams of glycine (free base) powder per gallon of estimated OPA volume should be sprinkled on the spill. The glycine should be thoroughly blended into the spill with a mop or other tool and allowed to neutralize the OPA for one hour.

3) The spill area should be mopped down with soap and water and then rinsed with water. All liquid should be flushed down the drain, followed by large amounts of water.

4) The cleanup tools should be rinsed with soap and water and then rinsed with large amounts of water. The rinse water should be discarded down the drain, followed by large amounts of water.

5) The neutralized OPA solution should be poured down the drain, followed by large amounts of water.

H.3.6 Disposal of OPA solutions

Spent OPA solutions should be disposed of in accordance with federal, state, and local regulations. Spent OPA solutions may be discarded down the drain if applicable regulations permit. Solutions containers should be rinsed according to label directions before being discarded.

H.3.7 Vapor monitoring

Gas, vapor, and droplet emissions can occur from manual use and even the best made equipment. Although the vapor pressure for OPA is low, OPA has potential health effects and odor is an unreliable indicator of the presence and concentration of OPA below hazardous concentrations. However, continuous gas/vapor monitoring systems are not currently available to detect potentially hazardous concentrations. Review the SDS and consult the suppliers of OPA-based disinfectants for advice on safe use.

H.4 Peracetic acid–hydrogen peroxide solutions

H.4.1 Introduction

Peracetic acid solutions exist as equilibrated solutions of hydrogen peroxide, acetic acid, peracetic acid, and water. They typically have a vinegar-like odor, which can be strong depending on the concentration of acetic acid and peracetic acid. The strong microbicidal effects and broad-spectrum activity of peracetic acid (also referred to as peroxyacetic acid) at relatively low concentrations have been known since the early 1900s (Freer and Novy, 1902 [154]; Block, 2001 [94]).

Peracetic acid alone is highly unstable and normally cannot exist without hydrogen peroxide and acetic acid. Therefore, all aqueous solutions of peracetic acid contain hydrogen peroxide. The relationship between the concentrations of peracetic acid, acetic acid, and hydrogen peroxide is determined by the composition of the mixture and the chemical equilibrium constant. Peracetic acid solutions can vary significantly, such as from 35 % peracetic acid and 6 % hydrogen peroxide to 5 % peracetic acid and 26 % hydrogen peroxide. Peracetic acid–hydrogen peroxide formulations can be formulated to include buffers, surfactants, and anticorrosive for specific applications. These will range in antimicrobial efficacy, safety considerations, and device compatibility. To ensure compatibility, users are advised to consult the medical device manufacturer's written IFU before using the product.

This section covers the properties and applications of peracetic acid–hydrogen peroxide solutions; occupational exposure considerations specific to peracetic acid and hydrogen peroxide, including vapor monitoring and procedures for handling spills; and the disposal of peracetic acid–hydrogen peroxide solutions.

H.4.2 Properties and applications of peracetic acid–hydrogen peroxide solutions

A variety of peracetic acid–hydrogen peroxide solutions are available for HLD and sterilant applications. They vary considerably in their antimicrobial activity and manufacturer's written IFU (including contact times, exposure temperatures, and reuse recommendations). They range in their peracetic acid and hydrogen peroxide concentrations, with typical HLD claims ranging from 5 to 30-minutes and sterilant contact times of 6-minutes to 8-hours.

One peracetic acid formulation is designed for single use in an automated system. This sterilant formulation is FDA-cleared for the liquid chemical sterilization of manually cleaned, immersible, reusable critical and semi-critical heat sensitive medical devices, including endoscopes and their accessories. Devices processed in this system are chemically sterilized using a peracetic acid LCS and rinsed with extensively treated, utility water. In this system, concentrated (35 %) liquid peracetic acid is diluted within a buffered system to its ~0.2 % (~2,000 ppm) "use dilution."

The labeled contact conditions for liquid sterilization are 6-minutes at 45.5 °C to 60 °C (114 °F to 140 °F). During the sterilization cycle, time and temperature are automatically controlled and monitored. The cycle is completed by rinsing with extensively treated utility water to remove sterilant residues. The processor treats utility water using a three-stage process: pre-filtration, UV irradiation, and 0.1 micron (μ) filtration.

The pre-filtration stage reduces particulates present in the utility water. The UV irradiation stage inactivates waterborne pathogenic viruses in the unlikely event that they are present in utility water. The dual membrane, 0.1 μ pharmaceutical sterilizing-grade filter effectively removes bacteria, fungi, and protozoa larger than 0.1 μm from the rinse water. The efficacy of this filtration process depends on the quality of the incoming utility water (EPA, 2012 [376]). The typical cycle time is about 23-minutes.

Chemical indicators designed for this system are available from the manufacturer. A spore test strip has also been cleared for use in this system. A variant of this system provides 0.2 micron filtered rinse water instead of extensively treated rinse water. This system is indicated only for use with semi-critical devices. It completes the same processing cycle using the same sterilant under identical exposure conditions in 18–19-minutes.

U.S. Department of Transportation shipping restrictions apply to concentrated solutions of peracetic acid (including 35 % to 43 % solutions), which are categorized as organic peroxides and corrosive. Special handling procedures for the concentrated liquid are listed in the manufacturer's SDS. Unless otherwise noted, the SDS applies only to the concentrate, not to the "use dilution" in the processor. Safety information about the diluted solution can be obtained from the manufacturer and other authoritative sources.

Prediluted and ready-to-use formulations are also available. These formulations are indicated for use in liquid chemical sterilization and HLD of cleaned, immersible, reusable medical and surgical devices. For example, one formulation contains 1 % hydrogen peroxide and 0.08 % peracetic acid; the contact time for sterilization is 8 hours at 20 °C (68 °F), and the contact time for HLD is 25-minutes at 20 °C (68 °F). This formulation is reusable for up to 14-days. Another formulation contains 8.3 % hydrogen peroxide and 7.0 °% peracetic acid; the contact time for sterilization is 5-hours at 25 °C (77 °F), and the contact time for HLD is 5-minutes at 25 °C (77 °F). This formulation is reusable for up to 5-days.

Unlike the more concentrated solutions, the ready-to-use solutions may not be labeled as skin irritants and may not cause dermal sensitization. Toxic inhalation effects can vary depending on the formulation, but users should avoid breathing the vapors. Formulations are considered corrosive to ocular tissue.

Peracetic acid–hydrogen peroxide solutions are typically formulated to include buffers, surfactants, and anticorrosives. These formulations vary in their efficacy, stability, and materials compatibility. Peracetic acid can be directly corrosive to metals, including copper, brass, and stainless steel, although these effects are significantly reduced by buffers and anticorrosives in individual formulations. Cosmetic material effects can include discoloration of colored aluminum and removal of paint from surfaces. As in all cases, it is recommended that before using a disinfectant, users should consult with the device and disinfectant manufacturers to ensure device compatibility.

Peracetic acid-hydrogen peroxide solutions are able to destroy and remove glutaraldehyde-protein deposits (Tucker et al., 1996 [315]) and discoloration when switching from glutaraldehyde- to peracetic acid-based disinfectants (Ofstead et al., 2017 [238]).The following effects can be observed in the transition period:

a) Brightening of the markings on the external surfaces of endoscopes;

b) Ease of cleaning instrument channels. Glutaraldehyde-protein deposits initially hamper cleaning with a brush, but this later subsides after a number of reprocessing cycles and complete elimination of the deposits (Biering, 2014 [92]).

H.4.3 Effective use of peracetic acid-hydrogen peroxide solutions

To ensure efficacy when using the concentrated formulation, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with peracetic acid–hydrogen peroxide solutions.

b) Devices should be disassembled and thoroughly cleaned. The reprocessor manufacturer's written IFU should be consulted regarding whether it is essential that devices be dry before processing.

c) The device and reprocessor manufacturers' written IFU for placing and connecting the device within the reprocessor should be followed.

d) The reprocessor manufacturer's written IFU should be followed.

e) The process should be monitored with a CI and/or a spore test strip as recommended by the reprocessor manufacturer.

f) Solutions should not be used beyond their shelf life.

g) The concentrated peracetic acid should be stored in a well-ventilated area at the temperature recommended by the manufacturer.

To ensure efficacy when using the prediluted formulations, the user should observe the following guidelines:

a) The medical device manufacturer's written IFU should be consulted to determine the compatibility of the device with peracetic acid–hydrogen peroxide solutions.

b) If an automated reprocessor is to be used, the manufacturer should be consulted to determine the compatibility of the equipment with the peracetic acid–hydrogen peroxide solution.

c) Devices should be disassembled and thoroughly cleaned and dried before they are immersed in order to prevent adding debris to the solution or diluting the solution, both of which can shorten the efficacy period.

d) Devices should be thoroughly and completely immersed in the solution to ensure that all surfaces are covered by the solution and that all appropriate lumens have been filled with the solution, as recommended.

e) A solution test strip or chemical monitoring device should be used to test the concentration of the active ingredients before each use. Only solution test strips or chemical monitoring devices recommended by the product manufacturer should be used. Quality control checks of the solution test strips, or chemical monitoring devices should be performed according to the manufacturer's written IFU.

f) When the concentration of the active ingredients falls below the MRC or MEC, the solution should no longer be used.

g) Solutions should be kept covered to prevent evaporation or formation of precipitate from airborne contaminants.

h) Solutions that evaporate below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded, and a fresh solution prepared.

i) Solutions should not be used beyond the reuse period indicated on the label even if the concentration of the active ingredients is at or above the MRC or MEC. (For the currently available products, the reuse period is 5- to 14-days.)
j) Solutions should not be used beyond their shelf life.
k) Unopened solutions should be stored in their original containers in a cool, well-ventilated area at the temperature recommended by the manufacturer.
l) Devices should be adequately rinsed in accordance with the manufacturer's written IFU prior to patient use.

H.4.4 Safe use of peracetic acid–hydrogen peroxide solutions

H.4.4.1 Occupational exposure

H.4.4.1.1 General considerations

Procedures should be developed that will prevent contact with peracetic acid–hydrogen peroxide solutions and reduce exposure to peracetic acid and hydrogen peroxide vapor. Personnel should always wear appropriate PPE when handling undiluted peracetic acid–hydrogen peroxide solutions (see H.4.4.1.4). The sterilant manufacturer's written IFU should be consulted regarding when personnel should wear appropriate PPE when using the diluted product.

H.4.4.1.2 Health effects of peracetic acid and hydrogen peroxide

H.4.4.1.2.1 Potential health effects of short-term exposure

The manufacturer's SDS and other authoritative sources such as National Research Council (2010) [218] should be consulted regarding potential health effects from exposure to peracetic acid. The effects of exposure can vary from product to product and manufacturer to manufacturer, depending on the concentration and exposure time. Eye contact with undiluted peracetic acid–hydrogen peroxide solutions is corrosive and can cause irreversible eye damage, including blindness. Skin contact with undiluted peracetic acid-hydrogen peroxide solutions can cause severe burns (FDA MDR 8180902, 2018 [362]); hydrogen peroxide burns are indicated by a whitening of the skin.

Inhalation of vapors and mists will irritate the eyes, nose, throat, and lungs. Coughing, breathing difficulty (FDA MDR 8551998, 2019 [361]), headaches (FDA MDR 8287449, 2019 [360]), and nausea (FDA MDR 8287449, 2019 [360]) can occur. Higher exposures can cause a buildup of fluid in the lungs (pulmonary edema), a medical emergency with shortness of breath (New Jersey Department of Health and Senior Services, 2004 [223]).

H.4.4.1.2.2 Potential health effects of long-term exposure

Long-term health effects vary with the concentration of the peracetic acid product and extent and duration of exposure. In addition to the short-term symptoms, high or repeated exposure can also affect the liver and kidneys (New Jersey Department of Health and Senior Services, 2004 [223]). The product SDS and other authoritative sources should be consulted to evaluate potential health hazards and any worker protection standards. Some peracetic acid–hydrogen peroxide solutions are considered sensitizing. Some formulations' ingredients, present at low concentrations, are listed by the IARC as ‘'possibly carcinogenic to humans."

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) [179] or the IARC website. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2022) [70].

H.4.4.1.3 Occupational exposure limits

There is no OSHA permissible exposure limit for peracetic acid, but there are recommended 8-hour TWA limits for hydrogen peroxide vapor (1 ppm) and acetic acid (10 ppm).

The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour work week.

The ACGIH®-recommended TLV® for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2022 [70]). ACGIH® recommends a 0.4-ppm short-term exposure limit (STEL) for peracetic acid; for acetic acid, ACGIH® recommends a 10-ppm TWA and a 15-ppm short-term exposure limit (STEL).

The EPA has published Acute Exposure Guidelines for peracetic acid, with an 8-hour TWA of:

- EPA AEGL 1: 0.52 mg/m^3 (0.17 ppm);
- EPA AEGL 2: 1.6 mg/m^3 (0.51 ppm);
- EPA AEGL 3: 4.6 mg/m^3 (1.3 ppm).

The AEGL limits are defined as follows (EPA, 2012b [317]):

- AEGL-1 is the airborne concentration, expressed as parts per million or milligrams per cubic meter (ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic non-sensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
- AEGL-2 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.
- AEGL-3 is the airborne concentration (expressed as ppm or mg/m^3) of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Peracetic acid can be detected by several methods, and monitors for continuously measuring the peracetic acid vapor concentrations in the workplace are also available.

H.4.4.1.4 Personal protective equipment and first aid

H.4.4.1.4.1 Eye protection

Personnel should wear safety glasses or goggles when handling peracetic acid–hydrogen peroxide solutions. If any eye contact should occur, the eye should be rinsed immediately with plenty of water for at least 15-minutes. Medical advice should be sought.

H.4.4.1.4.2 Skin protection

Rubber or neoprene gloves should be worn. If any skin contact should occur, the affected area should be washed with large amounts of water according to the manufacturer's written IFU and the SDS. If irritation occurs, medical advice should be sought.

H.4.4.1.4.3 Respiratory protection

See 4.4.4 of ANSI/AAMI ST58:2013/(R)2018 [14].

H.4.4.2 Ventilation

Peracetic acid–hydrogen peroxide solutions should be used in a well-ventilated area (see 4.3.7). For specific ventilation requirements, the chemical manufacturer's written IFU should be consulted.

H.4.4.3 Pouring solutions

The solution should be poured from the original container into a clean, dry immersion container by a method that will prevent employee contact with the solution and reduce exposure to peracetic acid and hydrogen peroxide vapor. Agitation and splashing during transfer should be minimized. Examples of methods for minimizing contact with the solution or vapor include the use of closed transfer devices, local exhaust hoods, and/or ductless fume hoods and strict adherence to the use of appropriate PPE.

Rationale: Avoiding contact with peracetic acid–hydrogen peroxide products prevent skin and eye injury. Minimizing agitation and splashing during transfer also minimizes the potential for increased vapor. See also H.4.4.1.2.

H.4.4.4 Transporting solutions

Transport of peracetic acid–hydrogen peroxide solutions in secondary containers such as trays or buckets should be avoided. If it is absolutely necessary to transport a solution to another area, that area should be properly ventilated, and a method of transport should be selected that will minimize the potential for spills and the possibility of personnel exposure to the solution of vapor.

Rationale: Transporting solutions in secondary containers increases the risk of spills. Spills increase the surface area and thus increase the potential for vapor to raise the air concentration above the exposure limits in H.4.4.1.3. Spills also increase the potential for skin and eye contact and irritation, as described in H.4.4.1.2.

H.4.4.5 Storing solutions

Peracetic acid–hydrogen peroxide solutions should be stored in vented, closed containers or systems in a well-ventilated area. Soaking containers should always be covered and clearly labeled, in accordance with the OSHA Hazard Communication Standard (21 CFR 1910.1200[f][5][i]) [230], with appropriate warnings, precautionary statements, and first-aid instructions. The surface area of the containers should be as small as possible; they should be narrow and deep rather than large, long, and shallow. The lid should be kept on the soaking container at all times except when items are being placed into or taken out of the solution. Automated systems should be designed to prevent the escape of vapor and liquid.

Unused peracetic acid–hydrogen peroxide solutions should be stored in a manner that allows for stock rotation. They should be disposed of after the labeled expiration date.

Rationale: A closed system will minimize evaporation of the peracetic acid–hydrogen peroxide solution and subsequent personnel exposure to vapor. The manufacturer’s expiration date should not be exceeded because the solution will no longer be effective.

H.4.4.6 Immersing items to be high-level disinfected or sterilized

Personnel should wear appropriate PPE when placing instruments or other items into the solution; this activity should take place in a properly ventilated area. The worker should gently place clean, dry items into the solution, taking care to disturb and agitate the surface of the solution as little as possible.

Personnel should ensure that their exposure to peracetic acid vapor does not exceed safe limits.

When manually irrigating or flushing the solution through internal channels or lumens of an instrument, personnel should be careful to avoid being splashed or sprayed with the solution. The syringe should be carefully filled with the solution and securely attached to the channel opening or all-channel irrigator. The solution in the syringe should be slowly pushed into the channel; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator. A new syringe should be used each time.

Gloved hands should be rinsed thoroughly with water before the cover is replaced on the solution container to avoid contaminating the surface of the container with solution. The instruments or other items should be allowed to soak for the amount of time and at the temperature designated by the manufacturer to achieve HLD or sterilization. (See the device manufacturer's written IFU for additional recommendations on HLD and sterilization.)

Devices to be sterilized or high-level disinfected in an automated reprocessor should be loaded in the reprocessor in accordance with the manufacturer's written IFU.

Rationale: These procedures will help prevent worker exposure to peracetic acid and hydrogen peroxide and help ensure the effectiveness of the HLD or sterilization process. Reuse of syringes for irrigation or flushing could lead to contamination of the solution.

H.4.4.7 Rinsing disinfected or sterilized items

Personnel should wear appropriate PPE when removing items from the solution or from a reprocessor that does not include rinsing in the cycle; this activity should take place in a properly ventilated area.

For devices that are processed manually or in a reprocessor that does not include rinsing in the cycle, personnel should remove the solution from the internal channels or lumens of the device before removing the device from the solution; this can be accomplished by flushing each channel several times with a syringe filled with air. Personnel should take care to avoid being splashed with the solution.

The device should be totally immersed in the solution, and the syringe should be securely attached to the channel opening or all-channel irrigator. The plunger should be pushed slowly; too much force can cause the syringe to disconnect from the channel opening or all-channel irrigator or cause the solution to squirt from the channel opening. The instruments should be gently removed from the solution and rinsed thoroughly in clean, utility water or (if the items are to be used in a sterile field) sterile water. (Workers should rinse their gloved hands with water and then replace the cover on the solution container.)

To remove all residual solution, personnel should rinse the external surfaces of the items and any removable parts with copious amounts of clean running water; should immerse them in successive containers of clean water (the rinse solution should be discarded after each use, not reused); or otherwise rinse the device in accordance with the manufacturer's written IFU.

For instruments with interior channels, each channel or the all-channel irrigator should be flushed several times with clean water until all residual solution is removed from the channels (at least 500 mL of water during each separate rinse, unless the instrument manufacturer instructs otherwise). The flushing procedure should be repeated with air. For instruments with interior channels, the channels should be flushed with 70 % to 90 % ethyl or isopropyl alcohol, followed by forced air, to facilitate drying. (However, see the device manufacturer's written IFU.)

The external surfaces of instruments should be thoroughly wiped dry with a sterile, non-linting cloth.

Some automated reprocessors include rinsing in the HLD or sterilization cycle.

Rationale: Proper procedures for rinsing, flushing, drying, and storing instruments will help prevent worker exposure to peracetic acid and hydrogen peroxide and help ensure that residuals of these chemicals are not introduced into patient tissue. Running water or successive immersions in water is recommended for rinsing in order to further dilute the solution and to prevent the retention of solution that could occur in standing water (Durante, et al., 1992 [141]).

H.4.4.8 Transport and storage of processed devices

After instruments or other items are removed from the reprocessor, they should be aseptically transferred and presented at the point of use or stored between uses according to the device manufacturer's written IFU and health care facility protocol.

H.4.5 Peracetic acid–hydrogen peroxide spills

In the case of undiluted peracetic acid–hydrogen peroxide solutions, all sources of ignition should be removed, and the area should be ventilated. Personnel wearing appropriate PPE should flush the material with large quantities of water until all material is dissolved (diluted 1:20). Unopened containers should be placed in a sink of water and submerged, then opened and diluted.

Spilled PAA solutions should be collected, confined, and diluted to a safe concentration, or absorbed into inert media and disposed of appropriately. The best method will depend on the size of the spill and concentration of the PAA/hydrogen peroxide and should be determined in advance as part of the facility's safety (hazard communication program) plan.

In the case of ready-to-use peracetic acid–hydrogen peroxide solutions, see the manufacturer's written IFU.

H.4.6 Disposal of peracetic acid–hydrogen peroxide solutions

Peracetic acid–hydrogen peroxide solutions should be diluted with at least 20 parts of water and then disposed of in accordance with federal, state, and local regulations. Undiluted material should not be allowed to enter storm or sanitary sewer systems. Peracetic acid–hydrogen solutions should not be mixed with hypochlorite solutions. Solution containers should be rinsed according to label directions before being discarded.

H.4.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of peracetic acid–hydrogen peroxide below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the peracetic acid–hydrogen peroxide, and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

H.5 Hydrogen peroxide gas sterilization

H.5.1 Introduction

Hydrogen peroxide gas sterilization processes are particularly suited for sterilizing heat-sensitive materials because temperatures within the load currently do not exceed 55 °C (131 °F) and sterilization occurs in a low-moisture environment. FDA-cleared hydrogen peroxide gas sterilizers, either with or without plasma, are currently available in the United States. This section covers the properties and applications of hydrogen peroxide gas sterilization; occupational exposure considerations, including vapor monitoring and procedures for handling spills; and sterilant disposal.

H.5.2 Properties and applications of hydrogen peroxide gas sterilization systems

Medical devices that should be sterilized are those that have been validated and indicated in device manufacturer's IFU for hydrogen peroxide gas sterilization. Since the cycle times and characteristics also vary among manufacturers and systems, the user should consult the device manufacturer's written IFU to identify suitable sterilizer and cycle type.

The currently available hydrogen peroxide gas sterilization systems follow similar steps for their sterilization processes. It involves the following sequential steps: items to be sterilized are placed into the sterilization chamber, the chamber is closed, and a vacuum is drawn. An aqueous solution of hydrogen peroxide is injected into the chamber, where it vaporizes and surrounds the items to be sterilized.

Different technologies employ different cycle characteristics. All of the currently marketed hydrogen peroxide gas sterilizers evacuate the chamber to a specific pressure in preparation for one or more repeated injections of hydrogen peroxide, which may include up to four identical injections. After the last injection, the sterilizer will go into a programmed aeration or a plasma phase sequence to reduce the hydrogen peroxide residual associated with the processed medical device. At the end of the process, no toxic residues are left, and the remaining oxygen and water vapor are exhausted into the room as byproducts. Items inside the chamber are now ready for use. Chemical and biological indicators are available and cleared by the FDA for the specific sterilizer that they are designed to monitor.

As in all cases, it is recommended that before using a sterilization system, users should consult with the device and sterilizer manufacturers to ensure device compatibility. The written IFU will specify any limitations, including the minimum internal diameter and length for any lumen-containing medical devices (such as rigid and flexible endoscopes). Liquids, powders, and items made from cellulose cannot be processed in these systems.

For additional information on vaporized hydrogen peroxide sterilization, see Block (2001) [94]; Rutala, et al. (1998) [278]; and McDonnell (2007) [210].

H.5.3 Effective use of hydrogen peroxide gas sterilizers

To ensure efficacy when using a hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

a) The medical device and sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with hydrogen peroxide gas sterilization.
b) No cellulose-based products should be included inside or outside the package to be sterilized. (Cellulose-based products such as towels, gauze, or paper are absorptive and can interfere with the sterilization process. These types of materials can cause cycle cancellation.)
c) Devices should be thoroughly cleaned and dried before sterilization because excessive moisture can cause cycle cancellation.
d) Ratcheted instruments should be unlatched.
e) Devices should be packaged in Tyvek®-Mylar® pouches, polypropylene wrap, or reusable rigid sterilization container systems cleared by the FDA for use in the specific type of hydrogen peroxide gas sterilizer.
f) To ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer's written IFU. For those processes that employ a plasma phase, and to prevent impeding plasma formation or arcing, personnel should not stack items or allow items to contact the RF electrode.
g) Chemical indicators and *Geobacillus stearothermophilus* biological indicators cleared by the FDA for use in the specific hydrogen peroxide gas sterilizer should be used to monitor the process.

H.5.4 Safe use of hydrogen peroxide gas sterilizers

H.5.4.1 Occupational exposure

H.5.4.1.1 General considerations

Procedures should be developed that will minimize exposure to hydrogen peroxide. Personnel should always wear appropriate PPE when using hydrogen peroxide gas sterilizers (see H.5.4.1.4).

H.5.4.1.2 Health effects of hydrogen peroxide

H.5.4.1.2.1 Potential health effects of short-term exposure

Contact with highly concentrated hydrogen peroxide solutions is corrosive and severely irritating to skin (FDA MDR 8693427, 2019 [353]; FDA MDR 8219836, 2019 [350]; FDA MDR 8574795, 2019 [352]), eyes (FDA MDR 9282407, 2019 [356]; FDA MDR 8978106, 2019 [354]), nose, throat, lungs, and the gastrointestinal tract. Eye contact can cause irreversible eye damage, including blindness. Inhalation of vapors or mists from highly concentrated hydrogen peroxide solutions can be severely irritating to the nose, throat, and lungs;(FDA MDR 9282407, 2019 [356]; FDA MDR 9239844, 2019 [357]) in severe cases, it can result in pulmonary edema and permanent lung damage.

H.5.4.1.2.2 Potential health effects of long-term exposure

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) [179] or the IARC website. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2022) [70].

H.5.4.1.3 Occupational exposure limits

The OSHA PEL for hydrogen peroxide is 1 ppm as an 8-hour TWA (29 CFR 1910.1000, Table Z-1) [227]. The ACGIH® recommended threshold limit value (TLV®) for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2022) [70].

The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour workweek.

H.5.4.1.4 Personal protective equipment and first aid

H.5.4.1.4.1 Eye protection

Direct hydrogen peroxide contact with the eyes can cause irreversible tissue damage. For any necessary eye PPE, see the manufacturer's written IFU. If eye contact occurs, the eyes should be immediately flushed with large amounts of water according to the manufacturer's written IFU and the SDS, and a physician should be consulted immediately.

H.5.4.1.4.2 Skin protection

When items have been properly prepared (thoroughly cleaned, rinsed, and dried prior to packaging) and the sterilization cycle successfully completes, the risk of hydrogen peroxide contact when removing the load from the sterilizer is negligible. However, as a precaution to protect users from potential hydrogen peroxide contact in the event that items have not been properly prepared, personnel should wear polyvinylchloride or nitrile gloves when removing items from the sterilizer after a cycle has canceled, or at any time the items in the load have any visible moisture or liquid, as hydrogen peroxide could be present (FDA MDR 8219836, 2019 [350]; FDA MDR 8527290, 2019 [351]; FDA MDR 8574795, 2019 [352]). If any skin contact with hydrogen peroxide should occur, the skin should be washed with large amounts of water according to the manufacturer's written IFU and the SDS.

H.5.4.1.4.3 Respiratory protection

Respiratory protection is not usually required during normal operation of the sterilizer. The manufacturer's written IFU should be consulted for information on respiratory protection needed in the event of a sterilizer malfunction or aborted cycle.

NOTE Overexposure is unlikely to occur unless there is a cycle cancellation and the items in the load have visible moisture or liquid.

H.5.4.2 Ventilation

Hydrogen peroxide gas sterilizers should be used in a well ventilated area.

H.5.4.3 Safety guidelines

To ensure safe use of the hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

a) Sterilant cassettes/cartridges or cups should be checked for integrity before use. Cassettes/cartridges or cups that are leaking should not be opened.

b) Gloves should be worn when disposing of spent cassettes/cartridges or cups and when removing packages from a canceled cycle.

H.5.5 Spills

Personnel should wear eye protection and chemical-resistant gloves when cleaning up spills. Spills should be contained and absorbed with an inert absorbent material and then placed in a disposable container. Spilled hydrogen peroxide solution should be kept away from combustible material.

H.5.6 Sterilant disposal

Hydrogen peroxide solutions must be disposed of in accordance with appropriate U.S. federal and state regulations and international regulations. If unaltered by use, hydrogen peroxide solutions may be disposed of by treatment at a permitted facility or as advised by the local hazardous waste regulatory authority. Solution containers should be rinsed according to label directions before being discarded.

H.5.7 Vapor monitoring

Vapor monitoring is recommended if there is the potential for the hydrogen peroxide vapor concentration to exceed the OSHA recommended permissible exposure limits. Emissions from properly operated and maintained chemical vapor sterilizers should be well below the OSHA PEL (see H.5.4.1.3), but sterilizers and exhaust systems, as with any other

complex equipment, can and sometimes do fail. If monitoring is deemed necessary, continuous personal and area monitors for hydrogen peroxide are commercially available.

Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide gas below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide solutions and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

H.6 Hydrogen peroxide–ozone sterilization

H.6.1 Introduction

Hydrogen peroxide–ozone sterilization processes are particularly suited for sterilizing heat-sensitive materials because temperatures within the load do not exceed 41°C (106 °F) and sterilization occurs in a low-moisture environment. One FDA-cleared hydrogen peroxide-ozone sterilizer is currently available in the United States. This section covers the properties and applications of hydrogen peroxide–ozone sterilization; occupational exposure considerations, including vapor monitoring and procedures for handling spills; and sterilant disposal.

H.6.2 Properties and applications of hydrogen peroxide–ozone gas sterilization systems

Hydrogen peroxide–ozone sterilization uses a single cycle for all types of loads. It has been cleared by the FDA for the sterilization of general instruments, rigid endoscopes, and flexible endoscopes, including multichannel gastrointestinal endoscopes such as duodenoscopes, colonoscopes, and gastroscopes. The items to be sterilized should be thoroughly cleaned and dried before sterilization following the device manufacturer's IFU. Chemical and biological indicators are available and cleared by the FDA for monitoring the sterilization process.

The currently available hydrogen peroxide-ozone sterilization process involves the following sequential steps.

a) Cleaned and packaged items to be sterilized are placed on the loading rack and into the sterilization chamber.

b) The chamber is closed, the cycle is started, and a vacuum is drawn.

c) An aqueous hydrogen peroxide solution is vaporized, injected in the chamber, and surrounds the items to be sterilized, until a pre-set pressure differential is achieved.

d) Ozone is injected into the chamber and surrounds the items to be sterilized. Ozone is generated from oxygen within the sterilizer's self-contained ozone generator.

e) The load is exposed to the sterilant for the specified time.

f) The sterilizer evacuates the sterilants from the chamber.

g) A second sterilization phase is executed and included repetition of steps c) to f).

h) The sterilizer goes into a programmed aeration sequence to reduce the hydrogen peroxide and ozone residual associated with the processed medical device. At the end of the process, no toxic residues are left, and the remaining oxygen and water vapor are exhausted into the room as by-products.

i) Items inside the chamber are now ready for use.

As in all cases, it is recommended that before using a sterilant, users should consult with the device and sterilizer manufacturers to ensure device compatibility. The written IFU will specify any limitations, including the minimum internal diameter and length for any lumen-containing medical devices (such as rigid and flexible endoscopes). Liquids, powders, and items made from cellulose cannot be processed in this system.

H.6.3 Effective use of hydrogen peroxide–ozone gas sterilization

To ensure efficacy when using the hydrogen peroxide gas sterilizer, the user should observe the following guidelines:

a) The medical device and sterilizer manufacturers' written IFU should be consulted to determine the compatibility of the device with the sterilizer system.

b) No cellulose-based products should be included inside or outside the package to be sterilized. (Cellulose based products such as towels, gauze, or paper are absorptive and can interfere with the sterilization process. These types of materials can cause cycle cancellation.)

c) The only lumened items that should be sterilized are those with lumen sizes cleared by the FDA for the hydrogen peroxide-ozone sterilizer being used. FDA-cleared lumen internal diameter and length vary among manufacturers and sterilizer models. The user should consult the sterilizer manufacturer's written IFU to identify specific items appropriate for sterilization.

d) Devices should be thoroughly cleaned and dried before sterilization because excessive moisture can cause cycle cancellation.

e) Any hinged instruments should be opened.

f) Devices should be packaged in Tyvek® pouches, polypropylene wrap, or reusable rigid sterilization container systems cleared by the FDA for use in the specific type of hydrogen peroxide-ozone sterilizer.

g) Only trays and mats recommended by the sterilizer manufacturer and cleared by the FDA for use with the sterilizer should be used.

h) To ensure adequate sterilant contact, personnel should load the sterilizer as recommended in the sterilizer manufacturer's written IFU and respect the recommended load temperatures.

i) Chemical indicators and *Geobacillus stearothermophilus* BIs cleared by the FDA for use in the hydrogen peroxide-ozone sterilizer should be used to monitor the process.

H.6.4 Safe use of hydrogen peroxide-ozone gas sterilizer

H.6.4.1 Occupational exposure

H.6.4.1.1 General considerations

Procedures should be developed that will minimize exposure to hydrogen peroxide and ozone. Personnel should always wear appropriate PPE when using hydrogen peroxide-ozone sterilizers (see H.6.4.1.5).

H.6.4.1.2 Health effects of hydrogen peroxide

H.6.4.1.2.1 Potential health effects of short-term exposure

Contact with hydrogen peroxide solutions is corrosive and severely irritating to skin, eyes, nose, throat, lungs, and the gastrointestinal tract. Eye contact can cause irreversible eye damage, including blindness. Inhalation of vapors or mists can be severely irritating to the nose, throat, and lungs; in severe cases, it can result in pulmonary edema and permanent lung damage.

H.6.4.1.2.2 Potential health effect of long-term exposure

Hydrogen peroxide is listed as a Group 3 carcinogen ("unclassifiable as to carcinogenicity to humans") by the IARC and as an animal carcinogen by ACGIH®.

NOTE IARC and ACGIH® carcinogen classifications have specific meanings and are based on specific types of evidence. For an explanation of the IARC carcinogen classifications, see IARC (2010) [179] or the IARC website. For an explanation of ACGIH® carcinogen classifications, see ACGIH® (2022) [70].

H.6.4.1.3 Health effects of ozone

H.6.4.1.3.1 Potential health effects of short-term exposure

Exposure to ozone causes dryness of the mouth, coughing, and eye, throat, nose, and chest irritation. Ozone exposure may cause breathing difficulties, headache, and fatigue, and it also may increase sensitivity to bronchoconstrictors, including allergens.

The sharp odor of ozone can be detected at low concentrations (0.01 to 0.05 ppm).

H.6.4.1.3.2 Potential health effects of long-term exposure

The effects of long-term exposure to ozone can include inflammation and permanent lung damage.

H.6.4.1.4 Occupational exposure limits

H.6.4.1.4.1 Hydrogen peroxide

The OSHA PEL for hydrogen peroxide is 1 ppm as an 8-hour TWA (29 CFR 1910.1000, Table Z-1) [227].

The ACGIH® recommended threshold limit value (TLV®) for hydrogen peroxide is 1 ppm as an 8-hour TWA (ACGIH®, 2022).

The NIOSH recommended exposure limit (REL) for hydrogen peroxide is 1 ppm as a time-weighted average for up to a 10-hour workday and a 40-hour workweek.

H.6.4.1.4.2 Ozone

The OSHA PEL for ozone is 0.1 ppm (8-hour TWA), and OSHA recommends using a STEL of 0.3 ppm (15-min TWA), through the latter is not currently enforceable. The ACGIH® recommended TLV®s for ozone range for 0.05 ppm TWA to 0.20 ppm TWA, depending on the conditions and duration exposure.

H.6.4.1.5 Personal protective equipment and first aid

H.6.4.1.5.1 Eye protection

Direct hydrogen peroxide contact with the eyes can cause irreversible tissue damage. For any necessary eye PPE, see the manufacturer's written IFU. If eye contact occurs, the eyes should be immediately flushed with large amounts of water according to the manufacturer's written IFU and the SDS, and a physician should be consulted immediately.

H.6.4.1.5.2 Skin protection

When items have been properly prepared (thoroughly cleaned, rinsed, and dried prior to packaging) and the sterilization cycle successfully completes, the risk of hydrogen peroxide contact when removing the load from the sterilizer is negligible. However, as a precaution to protect users from potential hydrogen peroxide contact in the event that items have not been properly prepared, personnel should wear polyvinylchloride or nitrile gloves when removing items from the sterilizer after a cycle has canceled, or at any time the items in the load have any visible moisture or liquid, as hydrogen peroxide could be present. If any skin contact with hydrogen peroxide should occur, the skin should be washed with large amounts of water according to the manufacturer's written IFU and the SDS.

H.6.4.1.5.3 Respiratory protection

Respiratory protection is not usually required during normal operation of the sterilizer. The manufacturer's written IFU should be consulted for information on respiratory protection needed in the event of a sterilizer malfunction or aborted cycle.

NOTE Overexposure is unlikely to occur unless there is a cycle cancellation and the items in the load have visible moisture or liquid.

H.6.4.2 Ventilation

Hydrogen peroxide-ozone gas sterilizers should be used in a well-ventilated area (see 4.3.7).

H.6.4.3 Safety guidelines

To ensure safe use of the hydrogen peroxide–ozone gas sterilizer, the user should observe the following guidelines:

a) Sterilant solution bottles should be checked for integrity before use. Bottles that are leaking should not be used. Users should not attempt to open sterilant solution bottles as they are designed to be safely loaded closed into the sterilizer.

b) Gloves should be worn when disposing of spent bottles and when removing packages from a canceled cycle.

c) The user should verify that the sterilizer has been installed in accordance with the manufacturer's written IFU and should follow the manufacturer's written IFU.

Users do not handle the ozone during the process and, by design, cannot be exposed to ozone.

H.6.5 Spills

Personnel should wear eye protection and chemical-resistant gloves when cleaning up hydrogen peroxide spills. Spills should be contained and absorbed with an inert absorbent material and then placed in a disposable container. Spilled hydrogen peroxide solution should be kept away from combustible material.

Ozone spills cannot occur because ozone is a gas that cannot be found in a liquid state at room temperature.

H.6.6 Sterilant disposal

Hydrogen peroxide solutions must be disposed of in accordance with appropriate U.S. federal and state regulations and international regulations. If unaltered by use, hydrogen peroxide solutions may be disposed of by treatment at a permitted facility or as advised by the local hazardous waste regulatory authority.

Ozone disposal is unnecessary for the currently available sterilization system. The sterilizer is designed so that all of the ozone produced is converted after use to oxygen by means of a catalytic converter.

H.6.7 Vapor monitoring

Vapor monitoring is recommended if there is the potential for the hydrogen peroxide or ozone concentrations to exceed the OSHA recommended permissible exposure limits. Gas and vapor emissions can occur from even the best made equipment and odor is an unreliable indicator of the presence and concentration of hydrogen peroxide or ozone gas below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release and provide record keeping. Review the SDS and consult the suppliers of the hydrogen peroxide solutions and the manufacturer of the sterilizer and the gas monitoring equipment for more information.

H.7 Ethylene oxide sterilization

H.7.1 Introduction

EO is a well understood and characterized low temperature sterilization process suitable for heat and moisture sensitive medical devices. This section covers the properties and applications of EO sterilization, occupational exposure considerations, and sterilant disposal. Also see ANSI/AAMI ST41 [12].

H.7.2 Properties and applications of ethylene oxide sterilization

Ethylene oxide is an efficacious sterilant because EO molecules can permeate through most polymeric materials while retaining integrity. EO has good materials compatibility with a wide variety of materials used in medical devices. EO can penetrate long narrow lumens, such as those in flexible GI endoscopes and is not typically limited by diameter or length. For many years EO sterilization was the primary low-temperature process used by hospitals for sterilization of

medical devices that were not compatible with steam sterilization. EO is still available and used in hospitals throughout the world, although other low-temperature technologies have reduced EO usage in many facilities because of faster cycle times. EO is used extensively in industrial sterilization of medical devices that are not compatible with radiation or steam sterilization.

The critical parameters for EO sterilization are:

— Time;

— Temperature;

— EO gas concentration;

— Relative humidity.

EO characteristics that allow good materials penetration trade-off is the devices must be aerated for sufficient time to remove residual EO prior to patient use. Aeration is a process that flushes heated air over the device to remove EO molecules as they dissipate from the surface of the device.

EO systems cleared for use in the U.S. healthcare facilities utilize 100 % EO single-dose gas cartridges of liquid EO. Under pressure and temperature, the EO is vaporized to become a gas. Typical cycle temperatures are 37° C to 55° C and exposure times range from 1-hour to 4-hours. The items in the chamber are then aerated for a time recommended by the device manufacturer, which typically ranges from 12- to 20-hours. Exposure and aeration are required to be completed in a single chamber.

Users of EO systems should refer to the device manufacturer's and the EO sterilizer manufacturer's written IFU for information on how to process the device, aeration times, and compatible packaging.

EO systems are monitored with FDA-cleared biological and chemical indicators used as quality control tools.

H.7.3 Effective use of ethylene oxide sterilization

To ensure efficacy when using EO sterilization, the user should observe the following guidelines:

a) The written IFU of the medical device manufacturer and the sterilizer manufacturer should be consulted to determine the compatibility of the device with EO sterilization.

b) Fluids should not be sterilized by this method.

c) Devices with lumens can be sterilized by EO. The sterilizer manufacturer's written IFU should be followed.

d) Devices should be thoroughly cleaned and dried before sterilization.

e) Any ratcheted instruments should be unlatched.

f) Devices should be packaged in nonwoven pouches or reusable rigid sterilization container systems.

g) To ensure adequate sterilant contact, the sterilizer should be loaded as recommended in the sterilizer manufacturer's written IFU.

h) Chemical indicators and self-contained biological indicators (using Ba*cillus atrophaeus)* cleared by the FDA for use with EO should be used to monitor the process.

H.7.4 Safe use of ethylene oxide sterilizers

H.7.4.1 Occupational exposure

H.7.4.1.1 General considerations

Procedures should be developed that will minimize exposure to EO and comply with the OSHA Ethylene Oxide Standard (CFR 29 1010.1047) [226] and other application regulations. (See AAMI TIR67 [25]).

EO must be handled with care due to its toxicological profile, and it is potentially flammable or explosive if not handled safely. Exposure to EO should be avoided.

H.7.4.1.2 Health effects of ethylene oxide

H.7.4.1.2.1 Potential health effects of short-term exposure

Contact with EO liquid or gas is toxic and can cause serious eye irritation, skin irritation, respiratory system damage, might cause drowsiness or dizziness, might cause cancer, and is suspected of mutagenic effects.

Exposure to EO should be avoided.

H.7.4.1.2.2 Potential health effects of long-term exposure

EO is listed with the following classifications:

a) Flammable Gas: Category 1;

b) Gas Under Pressure: Liquefied gas;

c) Acute Toxicity (inhalation): Category 3;

d) Serious Eye Damage/Irritation: Category 2A;

e) Skin Corrosion/Irritation: Category 2;

f) Reproductive Toxicity: Category 2;

g) Carcinogenicity: Category 1A;

h) Germ Cell Mutagenicity: Category 1B;

i) Specific Target Organ Toxicity (single exposure): Category 1;

j) Specific Target Organ Toxicity (single exposure): Category 3.

The following are guidelines for preventing exposure:

a) Obtain special instructions before use.

b) Do not handle until all safety precautions have been read and understood.

c) Keep away from heat/sparks/open flames/hot surfaces. No smoking.

d) Do not breathe gas/mist/vapors or spray.

e) Use only in a well ventilated area.

f) Wear protective gloves and eye/face protection.

g) Do not eat, drink, or smoke when using handling EO cartridges.

h) Wash hands thoroughly after handling.

H.7.4.1.3 Occupational exposure limits

The OSHA PEL for ethylene oxide is 1 ppm as an 8-hour TWA (29 CFR 1910.1947 [232]), and the OSHA recommended STEL is 5 ppm (29 CFR 1910.1947 [232]).

The ACGIH® recommended threshold limit value (TLV®) for ethylene oxide is 1 ppm as an 8-hour TWA (ACGIH®, 2022).

H.7.4.1.4 Personal protective equipment and first aid

H.7.4.1.4.1 Eye protection

Select and use eye/face protection to prevent contact based on the results of an exposure assessment. The following eye/face protection(s) are recommended: indirect vented goggles.

H.7.4.1.4.2 Skin protection

Select and use gloves and/or protective clothing approved to relevant local standards to prevent skin contact based on the results of an exposure assessment. Selection should be based on use factors such as exposure levels, concentration of the substance or mixture, frequency and duration, physical challenges such as temperature extremes, and other use conditions. Consult with the glove and/or protective clothing manufacturer for selection of appropriate compatible gloves and protective clothing.

Gloves made from the following material(s) are recommended: butyl rubber.

H.7.4.1.4.3 Respiratory protection

An exposure assessment might be needed to decide whether a respirator is required. If a respirator is needed, use respirators as part of a full respiratory protection program.

Based on the results of the exposure assessment, select from the following respirator type(s) to reduce inhalation exposure: full-facepiece supplied-air respirator.

For questions about suitability for a specific application, consult with the respirator manufacturer.

H.7.4.2 Ventilation

EO sterilizers should be used in a well ventilated area according to the sterilizer manufacturer's recommendations. The ventilation system should meet the requirements in the manufacturer's defined site planning and installation specifications. See also ANSI/AAMI ST41 [12].

EO gas must be ventilated to the outside or to an abatement device vented to the outside.

H.7.4.3 Safety guidelines

a) Do not use in a confined area with minimal air exchange. Do not handle until all safety precautions have been read and understood.

b) Keep away from heat/sparks/open flames/hot surfaces.

c) Take precautionary measures against static discharge. Do not breathe gas/mist/vapors/spray.

d) Do not get in eyes, on skin, or on clothing.

e) Do not eat, drink, or smoke when using EO.

f) Do not wear heavy perfumes as they can set off alarms.

g) Wear gloves and wash hands thoroughly after handling. Avoid release to the environment.

h) Eliminate all ignition sources.

i) Avoid contact with oxidizing agents (e.g., chlorine, chromic acid etc.)

j) Use personal protective equipment (gloves, respirators, etc.) as required.

k) Store cartridges in an upright position in an approved flammable liquid storage cabinet vented to the outside atmosphere, or in an area suitable for storage of flammable liquids appropriately vented to the outside atmosphere, or into a non-recirculating dedicated exhaust system, continuously.

l) Keep all sources of ignition away from the sterilizer and cartridges.

m) Check local fire protection codes for additional requirements.

H.7.5 Spills and leaks

If an EO cartridge is wet or feels cold to touch, it might be damaged or leaking. The following are guidelines for dealing with spills and leaks:

a) Evacuate the area. Eliminate all ignition sources if safe to do so. Keep away from heat/sparks/open flames/hot surfaces. No smoking.

b) Ventilate the area with fresh air.

c) With appropriate respiratory protection and PPE, seal the leaking container, if possible. Place leaking containers in a well ventilated area, preferably in an operating exhaust hood, or, if necessary, outdoors on an impermeable surface until appropriate hazard packaging for the leaking container or its contents is available.

d) Refer to manufacturer's SDS for information regarding physical and health hazards, respiratory protection, ventilation, and personal protective equipment.

H.7.6 Sterilant disposal

Empty cartridges should be disposed of in a chemical waste container according to facility policy.

Partial or full cartridges should be run in an empty sterilizer cycle.

EO is considered hazardous waste and must only be disposed of in compliance with applicable local/regional/national/ regulations.

H.7.7 Vapor monitoring

Gas and vapor emissions can occur from even the best made equipment, and odor is an unreliable indicator of the presence and concentration of ethylene oxide below hazardous concentrations. Continuous gas monitoring systems are available to help employers satisfy the requirement to provide a safe work environment by providing alerts in case of potentially hazardous concentrations, informing workers when it is safe to return after a release, and provide record keeping. Review the SDS and consult the suppliers of the ethylene oxide and the manufacturers of the sterilizer and the gas monitoring equipment for more information.

EO sterilizers currently used in the United States are designed in such a way that a leak is unlikely, because the system is under vacuum. If a leak occurs, EO will not be released, but air will enter the system. Pressure sensors are used to detect abnormal conditions.

Annex I
(informative)

Endoscope microbiocidal methods

There are a variety of biocidal methods available for disinfecting and sterilizing flexible endoscopes (see Section 8). Table I.1 provides characteristics of the available methods.

Table I.1—Characteristics of microbicidal methods for endoscope processing

Characteristic	High-level Disinfectants (HLD)	Liquid Chemical Sterilants (LCS)	Health Care Terminal Sterilization Systems
Composition of Biocide	Liquid	Liquid	Chemical Gas or Vapor
Manual Use Option (not recommended)	Yes	Yes	No
Manual Chemical Contact Time Required (fill and rinse time not included)	5 – 90-minutes	2 – 12 hours	Not applicable
Minimum Achieved Organism Kill	6 logs Most Resistant Mycobacteria species (1,000,000)	6 logs Most Resistant Bacterial Spore (1,000,000)	12 logs Most Resistant Bacterial Spore (1,000,000,000,000 [A])
Minimum Required Sterility Assurance Level (SAL)	Not applicable	Cannot be calculated for liquid based biocides	10^{-6} There is less than or equal to one chance in a million that a single, viable microorganism is present on a sterilized item[A]
Estimated Automated Cycle Time[B]	22 – 45-minutes or more depending on HLD used and other factors[B]	18 - 23-minutes	19-minutes – 15-hours
Quality Control Options	1) Physical parameters (time, temperature). 2) Minimum Effective Concentration (MEC) Solution Test Strip or Minimum Required Concentration (MRC) Solution Test Strip.	1) Physical parameters (time, temperature)Chemical Indicator, Minimum Effective Concentration (MEC) Solution Test Strip or Minimum Required Concentration (MRC) Solution Test Strip. 2) Spore Test Strip (automated system only).	1) Physical parameters. 2) External Chemical Indicators. 3) Internal Chemical Indicators. 4) Biological Indicators. 5) Process Challenge Devices for Routine Efficacy Testing (not readily available for H_2O_2-only sterilization systems).
Post Processing Conditions	Endoscope is wet post processing with nonsterile rinse water. Immediate drying is required. Perform drying according to endoscope manufacturer's written IFU.	Liquid chemically sterilized endoscopes intended to be used in a critical application should be used immediately after processing. They may also be used immediately in semi-critical applications. If not meant for immediate use, follow instructions for storage of high-level disinfected endoscopes.	Endoscope is ready for use, can be stored open when anticipated use is in soiled organs, or retained in sterile packaging (terminal sterilization) for subsequent anticipated use in sterile environments. If using EO sterilization, ensure proper aeration time is completed prior to use.

[A] Theoretical 12 logs most resistant bacterial spore (1,000,000,000,000) is based on doubling the 6-log reduction achieved during half cycle validation.

[B] Estimated time **excludes** cleaning, inspection, and packaging (when applicable); range is wide because processing time is dependent on many variables including, as applicable, endoscope, processing equipment, chemical IFU, processing temperature, water supply, and options selected.

Annex J
(informative)

Endoscope storage risk assessment

In addition to 11.2:

a) Endoscopes are stored so that residual fluid does not remain in the channels.

b) Endoscopes are stored, with their detachable parts dismantled, in a manner that keeps them secure and together with the endoscope as a unique set.

c) Endoscopes are stored suspended vertically in a cabinet designed for flexible endoscope storage, or horizontally, if so, instructed within the cabinet manufacturer's written IFU.

d) Tracking is available for each endoscope, including last episode of HLD.

e) If a storage cabinet is used, all manufacturer's written IFU should be followed and documented.

f) Endoscope internal channels receive additional drying by flushing with instrument quality air or HEPA filtered air even after AER processing or they are mechanically dried, verified to be dry or stored in a drying cabinet.

g) Non-linting cloths used to dry external surfaces.

h) Processed endoscopes are appropriately tagged with the date last processed.

i) Storage cabinet is kept closed.

j) If storage cabinets meet the standard EN 16442-2015 [47], the cabinet manufacturer recommends a maximum safe storage time based on validated test methods.

k) Processed endoscopes are handled with new, clean, non-latex gloves when moved from AER, to drying, to hanging and to the procedure room.

l) A method of air circulation (HEPA filter, instrument air, drying cabinet, etc.) is used.

m) Endoscopes are transported to the storage cabinet in accordance with Section 11.

Annex K
(informative)

Endoscope drying

K.1 Introduction

This annex reviews information about the importance of drying flexible endoscopes after processing, methods for flexible endoscope drying and the current state of drying verification. Drying of processed endoscopes lowers the risk of transmission of residual bacteria to subsequent patients. The collective research evidence, practice guidelines, and manufacturers' instructions for use (IFUs) all emphasize the importance of drying as a terminal step in endoscope processing to lower risk of microbial growth post-processing.

K.2 Importance of drying

Drying of gastrointestinal endoscopes after washing and high-level disinfection is an essential component in processing. Residual moisture allows microorganisms to survive and multiply. Because bacteria can double in population every 20- to 30-minutes, an inadequately dried endoscope contaminated with only one or two viable bacteria can, after eight hours of storage, be contaminated with tens of thousands to millions of bacteria, magnifying the risk of transmission of infectious organisms to the next patient Alfa, et al. [54]. Therefore, the exterior surface and all interior channels of flexible endoscopes should be thoroughly dried before reuse or storage.

K.2.1 Literature review

Research has demonstrated that several modalities, air types, and durations have been efficacious in the drying of flexible endoscopes. Forcing HEPA filtered or instrument air through endoscope channels facilitates drying, can evacuate and/or accelerate the evaporation of residual alcohol (if used), and reduces the likelihood of progressive contamination of the endoscope by waterborne pathogens.

In 1983, Gerding et al. [163] demonstrated that the institution of forced air drying significantly reduced bacterial contamination of stored endoscopes, presumably by removing the wet environment favorable for bacterial growth. In a 1991 study, Alfa et al. [54] demonstrated culture positive contamination in the majority of 21 processed endoscopes, with marked overgrowth of gram negative bacteria over the subsequent 48-hours of storage following processing. Without other interventions, the institution of 10-minutes of drying time using programmed cycles in an automated endoscope reprocessor (AER) following HLD, or tabletop delivery of forced medical air, through all channels markedly reduced contamination and prevented the proliferation of bacteria that had been seen in the absence of drying cycles. In a current era, study of drying modalities, Barakat et al. [78] demonstrated only a single water droplet in 69 endoscope cycles following 10-minutes of 'automated' forced filtered air purge of all channels, compared to modest numbers of persistent droplets after 5-minutes and extensive fluid after manual targeting of channels with a forced air gun. Perumpail et al., [254] recently demonstrated that use of a drying cabinet which directs compressed air into all endoscope channels yielded drying of all lumens within one hour. Multiple studies have demonstrated similar results, with superior drying by delivery of HEPA filtered medical air into all channels for sufficient durations [53], [213], [284], [247], [236], compared to absence of dedicated channel drying [236], use of brief air pistol flushing of channels [53], [246] or more limited 5-6 minute drying intervals [53], [242]. Reliance on vertical hanging storage alone, without prior dedicated channel flushing or prolonged flushing during storage does not yield reliably dry instruments [213], [236], [284]. No studies have directly compared 10-minutes of forced air drying of all channels to prolonged (1-hour or more) forced air channel drying in "drying cabinets." Table K.1 summarizes the elements or techniques in drying addressed in the published primary data.

Table K.1—Summary of endoscope drying studies and methods of evaluation

Study	Drying Time/ Modality	Microbial Culture	Humidicator	Borescope	Clinically Used	Simulated-Use
Gerding, 1982 [163]	X	X			X	
Alfa ,1991 [54]	X	X			X	
Saliou, 2015 [284]	X	X			X	
Ofstead, 2016 *(Assessing residual contamination)* [247]		X		X	X	
Osftead, 2016 *(Practical toolkit)* [236]		X			X	
Ofstead, 2017 *(Longitudinal)* [246]		X		X	X	
Ofstead, 2018 *(Residual moisture)* [242]	X	X	X	X	X	
Ofstead, 2018 *(*Bronchs*)* [237]	X	X		X	X	
Thaker, 2018 *(Duodenoscope reprocessing practices)* [310]						
Thaker, 2018 *(Inspection of endoscope channels)* [309]				X		
Barakat, 2019 *(Comparison of automated vs manual drying)* [78]	X	X	X	X	X	
Barakat, 2019 *(Simethicone retention)* [80]				X	X	
Perumpail, 2019 [254]	X	X	X			X
Barakat, 2018 *(Scoping the scope)* [79]				X	X	
Alfa, 2017 *(Sterile RO water)* [51]		X		X		X
Alfa, 2017 *(Novel PTFE-channel model)* [51]		X		X		X

K.3 Drying verification

Research has not yet established an acceptance criterion for adequate “dryness.” Verification of endoscope drying is challenging to accomplish due to the limitations imposed by the length and diameter of internal endoscope channels, the lack of validated technologies for confirmation of absolute exclusion of moisture and the limits of detection (LOD) of the few available test methods currently used. Existing written endoscope IFUs provided by the endoscope manufacturers state the endoscope must be thoroughly dry prior to being placed in storage, but they provide limited guidance on how to verify that end.

Given these conditions, the alternative for ensuring an endoscope is as dry as reasonably achievable include use of validated drying parameters of time, temperature, air flow, and humidity, or use of a test for detection of moisture. However, since at present there are no defined criteria by which all drying methods or devices are measured for effectiveness and validity. Performing the drying steps listed in the IFU may not provide the requisite assurance that an endoscope is reproducible dried. Therefore, it may be necessary to reevaluate the drying process as additional tools become available to verify effectiveness of drying.

The primary test used in research studies of endoscope processing efficacy, channel damage and retained moisture has been with direct observation with a video borescope [54], [236], [237], [246], [247], [284] with either real-time visual inspection or recorded video for offline review and documentation. A variety of borescopes of varying caliber, length, and image definition are available for many medical and nonmedical uses. It is important to understand that not all internal channels of an endoscope can be visualized using a borescope because channel features such as small internal diameter and/or sharp bends limit entry of the borescope into the channels. As a result, the limit of detection for borescope examination of residual moisture has not been established. In addition to the physical limitations (length,

diameter) and technical limitations (resolution, magnification), detection of moisture with a borescope presents a further challenge, as it requires cleaning and, likely, disinfection prior to inspection of the next flexible endoscope. Further, inspection of a fully processed endoscope likely requires that the endoscope itself be processed (at a minimum repeated HLD) after inspection. Hence, borescope inspection of every clinically-used endoscope after each use is likely not practical. A more practical approach, in most instances, is to use the borescope as part of a routine audit program that involves thorough visual inspection of an endoscope (see F.4 for guidance on determining sampling frequency). As part of the audit, a fully processed endoscope (including drying procedures) can be inspected for visible signs of moisture retention. Borescopes can also prove highly useful tools for inspection of endoscope channels during assessment for suspected damage, chronic culture positivity, or in studies of drying parameters.

Several studies [78], [242], [254] have employed moisture detection test papers, i.e., “humidicators,” containing cobalt chloride to qualitatively assess color change in the presence of moisture as a means of assessing drying. The assessment is performed by directing a 15 PSI air purge through the lumen of interest toward the detection paper positioned just below. In one study [254], testing for moisture in duodenoscopes was sensitive down to 250 µL of water per air water channel, 100 µL per suction-biopsy channel and 50 µL per elevator channel. Evaluation for moisture in the air-water and suction-biopsy channels of colonoscopes detected 100 and 150 µL of fluid [60]. Drying also correlated strongly with a reduction of inoculated bacteria over time.

Another study [242] correlated moisture detection using cobalt test paper to visual detection utilizing a borescope [59]. Test strips detected water in 22 endoscopes, of which 21 were visually confirmed (95 % positive predictive value for moisture detection). All 23 negative test strips yielded negative borescope exams as well (100 % negative predictive value).

K.4 Outstanding issues

Several questions pertinent to drying efficacy and efficiency remain unanswered and warrant investigation, including:

a) **What degree of endoscope drying after high level disinfection is necessary or optimal before patient use or endoscope storage?** Dryness is not a binary (i.e., “either-or”) state, and the degree of drying required to kill possible residual microbes after high level disinfection and to prevent microbial proliferation during storage is not clear. This will require understanding the relationship between degrees of dry, subsequent risk of pathogenic microbial presence and risk of transmissibility of infection.

b) What is the efficacy (best feasible performance in research settings) and effectiveness (performance in practice) of currently available methods for confirmation of endoscope drying after high level disinfection?

c) **What constitutes optimal quality assurance (QA) for endoscope drying performance?** This may include confirmation of adherence to established parameters (i.e., drying for a prescribed duration using correct air delivery systems, quality, and pressure) or use of validated moisture detection tools in a predetermined schedule to demonstrate consistent outcome of endoscope drying.

d) How do existing drying modalities compare in performance to achieve a dry endoscope when employing optimal air quality (i.e., HEPA-filtered or instrument air), air pressure, humidity, and temperature parameters? How do these drying modalities compare in cost effectiveness?

e) What are the optimal drying parameters (i.e., air quality, pressure, flow, temperature, and humidity) for varied endoscope channel lengths and diameters? Existing endoscopes have variable channel lengths and diameters, which undoubtedly will require different airflow parameters (i.e., pressure and time to dry) to achieve effective endoscope drying without causing damage to the endoscope.

f) What parameters for drying, including air quality, pressure, temperature, time, and endpoints, should be standardized for development of drying devices or cabinets and for incorporation into labelling claims? The variability among clinical practice recommendations and endoscope drying studies performed thus far make the development and standardization of drying equipment challenging.

g) What expectations for drying modalities, parameters, and durations should be included in endoscope manufacturers’ instructions for use (IFUs)?

h) Do different practices for handling, transport, and storage affect the condition of the endoscope during or subsequent to drying? Endoscope care following drying is important for the maintenance of a patient-ready endoscope.

K.5 Summary

Drying of endoscopes remains one component of processing for which inconsistent expectations and performance may contribute to ongoing risk of infection transmission. Current evidence suggests drying an endoscope with forced air through all channels may be employed to limit this risk. This can be accomplished with several varied devices and cabinets for delivery of airflow through the channels. Methods for detecting moisture, including borescopes and moisture detection test papers, have been used in research studies, but have not been standardized or validated for regular clinical use. Most guidelines from domestic and international organizations have incorporated guidance on drying, with varied detail regarding modalities and monitoring of performance [46] [47] [68].

K.6 Commonly accepted terminology

- Storage Cabinet: Designed to store endoscopes in the vertical position. Such cabinets do not have forced air circulation but generally do have ports to allow passive air flow through the cabinet.
- Conventional Storage Cabinet: Designed to store endoscopes in the vertical position with HEPA filtered forced air circulated throughout the cabinet. Air may or may not be forced into the lumens of the endoscope.
- Drying Storage Cabinet: Designed to store endoscopes with forced air flow (instrument quality or at a minimum HEPA filtered) directed into the lumens of the endoscope utilizing direct channel attachments to completely dry the internal channels of the endoscope within a set amount of time. Some cabinets are validated to store the endoscope for a specific period of time without microbial growth.
- Drying Aid: A device used to assist in the drying of the endoscope. HEPA filtration required as a minimum standard.
- Manual (Mechanical) Drying: Drying of channels by manual direction of compressed air into the channels of an endoscope with a compressed air gun.
- Compressed Air: Air that has been compressed to a pressure higher than atmospheric pressure.
- HEPA: High Efficiency Particulate Air is filtered to a minimum of 99.97 % or .3 microns.
- Automated Drying: Using a device or apparatus to direct a specific amount of compressed air for a pre-determined amount of time into all the channels of an endoscope to dry the endoscope.
- Instrument Air: As defined by ANSI/ISA S-7.0.01, is controlled for Particulate, Moisture, and hydrocarbons.
- Medical Air: As defined by ISO and ANSI standards is utilized for patient respiration and has minimum and maximum standards for Particulate, Moisture, and Oils as well as oxygen and nitrogen. This type of air is not necessary to be used to dry endoscopes.

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